	F DEFICIENCIES	(X1) PROVIDER/SUPPLIE	R/CLIA	(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
AND PLAN OF		IDENTIFICATION NU	MBER:	A. BUILDING:		CONFEE	
		440740		B. WING		C 07/02/2013	
		110748	STREET ADI		STATE, ZIP CODE		
NAME OF PROV	VIDER OR SUPPLIER		- anj	UTCHFIELD		•	
THE BAKER	R CLINIC FOR WO	MEN		NC 27704		and the second s	
(X4) ID	SUMMARY STA	ATEMENT OF DEFICIENCIE	S	ID D	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOL	ION (X5)	
PREFIX TAG	(EACH DEFICIENC) REGULATORY OR L	Y MUST BE PRECEDED BY .SC IDENTIFYING INFORM	ATION)	PREFIX TAG	CROSS-REFERENCED TO THE APPRODEFICIENCY)	OPRIATE DATE	
	11771 A 1 . O O 3 45 457 5 1	TO		E 000	The Baker Clini for Wome	nhar 7/19/13	
E 000 IN	NITIAL COMMEN	15			the south of the	tat there	
0	on July 2, 2013, st	taff with the Acute an	d Home		John Steps to enguine	ent	
C	are Licensure an	d Certification Section	n		er no polemen onthe	Ospha	
sı	urveyed The Bak	er Clinic for Women.	The	į	threat to the health a	1 100	
1 51	urvey findings rev	realed a potential imrand and safety of patien	inion its. Based		to to be taking the	e followy	
0	in the survey findi	ings, the facility failed	to ensure	: 1	of portents at Al	and	
a	uality control was	performed in blood	banking.		Steps. A guilty contro	and will	
T	he facility failed t	o perform quality cor	trol ^e testing	i	quelete assessment moy	the state of	
0	on one hundred-e sh(D) toeting: fails	ight patients that rece ed to ensure the ALB	Aclone	المارين المارين	The lemented and t	estry	
A .	Anti-D blood grou	ping reagent manufa	cturer's	Ì	we impressed the t	raned	
l la	erformance spec	cifications were verifie	ed prior to	1	person Net was 1 +		
þ	patient testing, fai	led to ensure a positi	ve and		to bollow manufacta	TO C	
i in	negative red blood	d cell control material ce daily when Rh(D)	i Was feeting was		I times for perform	ing	
l l	ested at least ont performed: failed	to follow manufacture	er's		institute to a inculat	ian of	
1	nstructions for pe	erforming Rh(D) testir	ng; failed to		quality control to per	forming	
l c	define an accepta	able room temperatur	e range in		the turing, and To	tell	
1	accordance with	manufacturer's instru	ctions for		If the appropri	1 of	
	ine performance :	of Rh(D) testing; and nd procedures were (developed	1	Herling A	quality	
	for staff impleme	ntation for the perform	nance of		templistere range	been	
	patient Rh(D) tes	ting using the ALBAC	lone Anti-D)	arressment plan from 1.		
	blood grouping re			Ì	to dentif	y and	
	During the curve	y at 11:55AM on July	12 2013.	i	to the problem	is. The	
	an Immediate Je	opardy was identified	in		forest future	a	
	immunohematolo	ogy and immediately		į	lab Queeler har hold	out tout	
1	communicated to	the physician owner	of the	.	qualified Technical Co	1)	
		mediate jeopardy wa	s not abate	a į	1. To moviding	oblish	
	during the onsite	survey.			to assir in toring	and	
	Therefore, based	d on in-office review,	it is the	, ,	Experience John A	L.A	
1	finding of this ag	ency that the facility I	าลร		direction for me that	taulit	
	neglected to prov	vide the services to a	ssure the		ent assessment poli	en com	
		d welfare of the clien vey findings, the Sect			granesentative N.	umbles	
	substantiated Ru	ule violations that incl	ude:		a a fact to test	edhor	
	Daroun illum 110	ere tresmination miles in the			The 103 photos 100	ts NO	
1					ween our wind happy		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE A CONTROLLED

A BUILDING: 110748 STREET ADDRESS, CITY, STATE, ZIP CODE 400-B CRUTCHFIELD ST DURHAM, NC 27704 SUMMARY STATEMENT OF DEFICIENCIES THE BAKER CLINIC FOR WOMEN SUMMARY STATEMENT OF DEFICIENCIES (EACH DEPTICIENCY MIST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) E 000 Continued From page 1 10 NCAC 14E0302 Person in Authority 10 NCAC 14E0309 Laboratory Services Findings reveal that, conditions at The Baker Clinic for Women, present an imminent danger to the health, safety and welfare of the clients and that emergency action is required to protect the clients. Pursuant to North Carolina General Statutes N.C.G.S. § 150B-3(c), the Division of Health Service Regulation (DHSR), North Carolina Department of Health and Human Services (DHHS), HEREBY SUMMARILY SUSPENDS YOUR CERTIFICATE TO OPERATE The Baker Clinic for Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic For Women and ADDRESS, AND ARE HEREBY DIRECTED TO CLOSE THE BAKER CLINICAL STATEMENT OF COMPANY AND ACTES THE PROPRIOR AND ACTES		T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIF	ER/CLIA	(X2) MULTIPI	E CONSTRUCTION	(X3) DATE S	
NAME OF PROVIDER OR SUPPLIER THE BAKER CLINIC FOR WOMEN OVA; ID. OVA; ID. FREETY TAG EQUILATORY OR LSC. IDENTIFFING INFORMATION) EQUILATORY OR LSC. IDENTIFFING INFORMATION) E 000 Continued From page 1 10 NCAC 14E. 0302 Person in Authority Findings reveal that, conditions at The Baker Clinic for Women, present an imminent danger to the health, safety and welfare of the clients and that emergency action is required to protect the clients. Pursuant to North Carolina General Statutes N.C. G.S. § 150B-3(c), the Division of Health Service Regulation (DHSR), North Carolina Department of Health and Human Services (DHHS), HEREBY SUMMARILY SUSPENDS YOUR CERTIFICATE TO OPERATE The Baker Clinic for Women, by NO LATER THAN 5:00 O CLOCK P.M. ON July 5, 2013. E 131 ONORC 14E. 0302 Person in Authority The governing authority shall designate a person to have authority and responsibility for the administrative and professional functions of the clinic. This Rule is not met as evidenced by: Based on record review, procedure review, observation, and interviews July 2, 2013, the facility's governing authority failed to ensure laboratory systems were in place to monitor and evaluate the overall quality of testing in the					A. BUILDING		COMPL	-1
THE BAKER CLINIC FOR WOMEN THE BAKER CLINIC FOR WOMEN OCCUPANT OF CHARACTER STATEMENT OF DEPICIENCES OF DEPARTMENT OF DEPICIENCES OF DEPARTMENT OF DEPICIENCES OF DEPARTMENT OF DEPICIENCES OF DEPARTMENT OF DEPICIENCES (EACH DEPICIENCE WILLST BE PRECEDED BY TULL REGULATORY OR U.S.C. IDENTIFYING INFORMATION) E 000 Continued From page 1 10 NCAC 14E0302 Person in Authority 10 NCAC 14E0309 Laboratory Services Findings reveal that, conditions at The Baker Clinic for Women, present an imminent danger to the health, safety and welfare of the clients and that emergency action is required to protect the clients. Pursuant to North Carolina General Statutes N.C.G.S. § 150B-3(c), the Division of Health Services (DHHS), HEREBY SUMMARILY SUSPENDS YOUR CERTIFICATE TO OPERATE. The Baker Clinic for Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic for Women, BY NO LATER THAN 5:00 O CLOCK P.M. ON July 5, 2013. E 131 .0302 PERSON IN AUTHORITY 10A NCAC 14E .0302 Person in Authority The governing authority shall designate a person to have authority and responsibility for the administrative and professional functions of the clinic. This Rule is not met as evidenced by: Based on record review, procedure review, observation, and interviews July 2, 2013, the facility's governing authority leaded to ensure laboratory systems were in place to monitor and evaluate the overall quality of testing in the	·		110748		B. WING			1
THE BAKER CLINIC FOR WOMEN CACH ID SUMMARY STATEMENT OF DEFICIENCIES DIRHAM, NC 27794 DIRHAM, NC 2779	NAME OF D	POVIDER OR SUPPLIER	110170	STREET AD	DRESS, CITY,	STATE, ZIP CODE		
PREFIX TAG RESULATORY OR LSC IDENTIFYING INFORMATION) E 000 Continued From page 1 10 NCAC 14E. 0302 Person in Authority 10 NCAC 14E. 0309 Laboratory Services Findings reveal that, conditions at The Baker Clinic for Women, present an imminent danger to the health, safety and welfare of the clients and that emergency action is required to protect the clients. Pursuant to North Carolina General Statutes N.C.G.S. § 150B-3(c), the Division of Health Service Regulation (DHSR), North Carolina Department of Health and Human Services (DHS), HEREBY SUMMARILY SUSPENDS YOUR CERTIFICATE TO OPERATE The Baker Clinic for Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic for Women, 8Y NO LATER THAN 5:00 O CLOCK P.M. ON July 5, 2013. E 131 0.302 PERSON IN AUTHORITY 10A NCAC 14E. 0302 Person in Authority The governing authority shall designate a person to have authority and responsibility for the administrative and professional functions of the clinic. This Rule is not met as evidenced by: Based on record review, procedure review, observation, and interviews July 2, 2013, the facility's governing authority failed to ensure laboratory systems were in place to monitor and evaluate the overall quality of testing in the	,		MEN					
10 NCAC 14E0302 Person in Authority Services Findings reveal that, conditions at The Baker Clinic for Women, present an imminent danger to the health, safety and welfare of the clients and that emergency action is required to protect the clients. Pursuant to North Carolina General Statutes N.C.G.S. § 150B-3(c), the Division of Health Service Regulation (DHSN), North Carolina Department of Health and Human Services (DHHS), HEREBY SUMMARILY SUSPENDS YOUR CERTIFICATE TO OPERATE The Baker Clinic for Women, an abortion clinic. YOU ARE HEREBY DIRECTED TO CLOSE The Baker Clinic for Women, BY NO LATER THAN 5:00 O' CLOCK P.M. ON July 5, 2013. E 131 D302 PERSON IN AUTHORITY 10A NCAC 14E0302 Person in Authority The governing authority shall designate a person to have authority and responsibility for the administrative and professional functions of the clinic. This Rule is not met as evidenced by: Based on record review, procedure review, observation, and interviews July 2, 2013, the facility's governing authority failed to ensure laboratory systems were in place to monitor and evaluate the overall quality of testing in the	PREFIX	(FACH DEFICIENC	Y MUST BE PRECEDED BY	Y FULL	PREFIX	(EACH CORRECTIVE ACCROSS-REFERENCED TO	TION SHOULD BE THE APPROPRIATE	COMPLETE
Findings include:		Authority 10 NCAC Services Findings reveal the Clinic for Women, the health, safety that emergency acclients. Pursuant to North N.C.G.S. § 150B-Service Regulation Department of He (DHHS), HEREBY YOUR CERTIFIC Clinic for Women HEREBY DIRECT Clinic for Women CLOCK P.M. ON 10A NCAC 14E. The governing auto have authority administrative and clinic. This Rule is not Based on record observation, and facility's governing laboratory system evaluate the overspecialty of Immediate in the control of the c	14E. 0302 Personal Laborate, conditions at The present an imminent and welfare of the cliction is required to proceed the present an imminent and welfare of the cliction is required to proceed the process of the cliction is required to proceed the proceed to proceed the process of the cliction of the cliction of the process of the procedure of the procedure of the process of the procedure of the process of the procedure of the process of	Baker it danger to ients and rotect the ratutes Health rolina vices PENDS The Baker OU ARE Baker AN 5:00 O' nority ite a person r the ions of the eview, 013, the ensure nonitor and	E 131	patients has been which explains a seiting has been only auges the preturn for reproportional contractional contra	en drafted n issue with adentified strent to t testing at	7/17/13

	of Health Service Re	egulation				(VA) DATE CUDICEV
STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLI	ER/CLIA		LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
AND PLAN	OF CORRECTION	IDENTIFICATION N	NAIDEL/	A. BUILDING	•	
						C
		110748		B. WING		07/02/2013
NAME OF P	ROVIDER OR SUPPLIER		STREET ADD	DRESS, CITY,	STATE, ZIP CODE	į
			400-B CR	UTCHFIELI	ST	1
THE BAH	(ER CLINIC FOR WO	MEN	DURHAM,	NC 27704		
(X4) ID PREFIX TAG	(FACH DEFICIENC	ATEMENT OF DEFICIENCI Y MUST BE PRECEDED B' LSC IDENTIFYING INFORM	Y FULL	ID PREFIX TAG	PROVIDER'S PLAN OF CORF (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE COMPLETE
E 131	Continued From p	age 2		E 131	conect temp range	specified 7/17/13
	1 The laboratory	failed to have a com	plete and	! : :	by manufacturer (At	actioned by
	current procedure	manual for performi	ng Rh.(D) 🦠		1) I specifie	cation
	testing using ALB/	Acione Anti-D blood	grouping	(A performance of	outlen
	reagent (see .0309	9(C)).			procedure for very An	to Durgent
		F-111 to these	Dh/D)		Stating any Men for	Le tol and
	2. The laboratory	failed to ensure that med at the temperat	KN(D)	1	100 le approved,	Latit
	enacified by the m	med at the temperations anufacturer (see .03	r08(C)) are	1	1. O sepropulary	no to patant
	Specified by the th		.00(0)).		ventred aft) Aqually
	3. The laboratory	failed to ensure that	the		festing (Attachment	een established
	ALBAclone Anti-D	blood grouping read	gent		test policy has	reen established
	manufacturer's pe	erformance specifica	tions were	****	learned !	Controls die
		tient testing was initi	ated (see		to ensue	feeting (see
	.0309(d)).			ļ	Lated each day	festing personal
	4 The leberators	failed to ensure that	t a noeifive	[THE TO ALL	ferting pace
	and negative red	blood cell control ma	terial was		Attachment I	to follow
	tested at least on	ce each day when R	h(D) testing	į	have been trained	turtions
	was performed (s				manufacturers ins	1 to the
				į	Dayformeny Kh	1) yearing
	5. The laboratory	failed to follow the	. 51.65		10 / + F) T	esting personal
		structions for perform	ming Rn(D)	Ì	(Attachment =)	Somme
	testing (see .0309	9(G)).		ì	I heer gwen ar	inst _
	6 The laboratory	failed to perform an	d document	v annah.	(Attachment E). To bove been given an regarding correction	re action
	corrective action	on 15 days when roo	om	}		COUNT TO TOTAL
	temperature was	outside the manufac	cturer's	1	requient when	5. The QA
	specifications for	performing Rh(D) to	esting. Ŕh(D))	is outside limit	5 The Cer
	testing was perfo	rmed and reported o	on 16	ļ	is on the	ncludes the
	patients on 10 of	the 15 days when the	e room	}	bookbach andy	anale that
		not within the manu	racturers		11/2 extrents on the	A toma
	specifications (se	.(u)evcv. ee		· ·	lested when	me rang
	7 The laboratory	failed to have a qua	litv	Ę	to the access	table limels.
	assessment plan	and failed to perfor	m and	•	was our say	100 avalite
	document quality	/ assessment activiti	es in the	•	(Attachment to). At	Jean Jan 7
	general laborato	ry system, analytic s	ystem and	į !	t rlancho	r ven
	post-analytic sys	tem to monitor, iden	tify and	ļ	assessed which	assures, ,
		s in the specialty of			anylemented which	newl, lab 1/17/13
1	Immunohematol	ogy (see .0309(d)).		ļ	ICH WIMMEN	, car

변경 (1985년 1987년) - 1987년 - 1987년 (1987년)	FORM APPROVED
(X2) MULTIPLE CONSTRUCTION A. BUILDING:	(X3) DATE SURVEY COMPLETED
	ł c

		110748		B. WING		07/02/2013
NAME OF PROVIDER OR SU	JPPLIER		STREET AD	DRESS, CITY,	STATE, ZIP CODE	
THE BAKER CLINIC F		MEN		UTCHFIELI , NC 27704		
OPERIV (FACH DE	EFICIENC'	TEMENT OF DEFICIENCIE MUST BE PRECEDED BY SC IDENTIFYING INFORM	FULL.	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROVIDERICIENCY)	D BE COMPLETE
systemic prinability to expatient Rh(linding of the provide the and welfare and welfare 10A-14E .0 have instrustion (2) Information (2) Information (2) Information (2) Information (2) Information (2) Information (3) Information (4) Information (5) Information (6) Information (7) Information (8) Information (8) Information (9) Information (10 Inform	y, the curoblems ensure to be the ensure to be serviced as serviced at the ensure to t	imulative effect of the resulted in the labor he accuracy and reliand results. Therefore the that the facility needs to assure the healt clients. TORY SERVICES The facility shall or each test need, including: gents, standard and ures; and neerning the basis nall ranges. The laboratory produces are evidenced by: of the laboratory produced in the laboratory produced in the laboratory produced in the laboratory produced in the laboratory staff failed in temperature ranges in the manufacturer's efformance of Rh(D) tive and negative Rh ach day that patients to follow the manufacturer's forming Rh(D) testing reforming Rh(D) testing results according to the laboratory staff failed and negative Rh ach day that patients to follow the manufacturer's reforming Rh(D) testing reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed and reforming Rh(D) testing results according to the laboratory staff failed according to	atory's ability of a, it is the eglected to th, safety edure fuct insert, the of 2013 terviews, a not erformed in ed to define e which s testing; (D) quality s were cturer's ng. I failed to tep	E 154	post-analytical systems, post-analytical systems, analytical systems, analytical systems, prostered to identify and problems in immuniphen Attachment G) A qualified invalidation of the lab director maintaining compliance procedure Harming and the string of the lab director of the last feet and and potients feet and been to an adverse conditions of the have been trained on the string sorte from the procedure for excellent, them reflex excellent, them reflex excellent, them reflex excellent, accuracy of firting sortes been written which includes the history with the Albah Atti-D waget. He fore accuracy of the string with the Albah Atti-D waget. He from the Albah Atti-D waget. He procedure for the string with the Nich Atti-D waget. The procedure of the string was the Albah the Nich apparent of festing. No apparent of festing. No apparent of festing to patents on the string was to patents on the string to patents on the string was the parent of festing. No apparent of festing to patents on the string was to patents on the string when done to patents on apparent of festing to patents of the patent	conect stology technical state of the state

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

Division of	of Health Service Re	egulation				(X3) DATE SURVEY
STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIE	R/CLIA		LE CONSTRUCTION	COMPLETED
AND PLAN	OF CORRECTION	IDENTIFICATION NU	MDELY.	A. BUILDING		_
			ļ		·	C
		110748		B. WING		07/02/2013
NAME OF P	ROVIDER OR SUPPLIER		STREET ADI	DRESS, CITY,	STATE, ZIP GODE	
				UTCHFIELI		
THE BAK	ER CLINIC FOR WO	MEN ,	DURHAM,	NC 27704		
	TP VOAMANIO	ATEMENT OF DEFICIENCIE	S	iD	PROVIDER'S PLAN OF CORRECT	TION (X5)
(X4) ID PREFIX	(EACH DESIGIENC)	Y MUST BE PRECEDED BY	FULL	PREFIX	(EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPL	OULD BE COMPLETE DATE
TAG	REGULATORY OR I	SC IDENTIFYING INFORM	ATION)	TAG	DEFICIENCY)	
				} ;	H 1 H OA ladebox	haudit. 7/12/13
E 154	Continued From pa	age 4		E 154	mony me an root	aveleen !
	, ,	LBAcione Anti-D bloc	nd		Professioner tent of stores of	
	testing using the A	The laboratory had a	copy of	}	vermate and reflect as	mary of
	the manufacturer's	instructions for use	of	i	decurate and reference	The Rh
	Al BAclone Anti-D	blood grouping reag	ent, dated		at leting procedure	Now
	2009, in the labora			:	potrent testing processine	+1
	, !	•			contains alguality con	poc
	The laboratory pro	ocedure titled "Lab Pr	ocedures"		control on how to firt	36
	states "1. Record	refrigerator and room)		Section on	frequency
	temperature in the	lab 2. Bring reagent	s to room		material what to use	on the
	temperature (20*-	30*) 3. Run controls /indicated (Lab Log).	And record	1	1 1 to home to perfor	in the
	Perform fingeretic	k: Hgb testing: fill m	o. icrocuvette		of fering isternet	the feeling,
	with blood place	in Hemocue, read in	45 secs.		feet how to many	to take
	(Range 11.0-16.0	grams) Rh testing:	Mix 1 drop		ful passetive action	11 4
	blood and 1 drop	of Anti-D Reagent or	ı slide, rock		The transfer of the	like I've
	gently (mix) for 30) seconds; incubate (observe)	j	obcedure also include	sastep
	for 5 minutes at F	Room temp if needed	•		procedure also include for	using
	(Agglutination = F	Rh positive, no Agglut	ination= Kr	1	ates procedure	C. C. C. T.
	negative)"			ł	by step procedure BG	Juagan
	The ALBAdone	Anti-D blend product	insert	-	control for Arti-D.	Attachund
	(70/1110PI/02 J	ine 2010) RECOMM	ENDED	į	control for	A Altria
	TECHNIQUES st	tates "Slide Techniqu	e Add 1	1	1) M. mocedaye wa	num
}	drop of blood gro	uping reagent to an			1 Parlier	pean 1.
	appropriately pre	pared area of a glass	s slide e.g. i	a į	A) The procedure was includes a back-up	mothered
	wax pencil oval.	Add 1 drop of red blo	ood cells		resets of fine	unacceptable
	suspended to 30	-45% in group homol	ogous		waitable	
	plasma/serum.	Mix well by rocking th	te the test	• • • • • • • • • • • • • • • • • • • •	try Af	ighther
	approximately at) seconds and incuba 18-24 degrees C with	nocasiona	1	Attachment	edure is
	miving After inc	subation, immediately	observe	.	I lood collection f	0
	macroscopically	for agglutination. Thi	s may be		the man	uck o
	facilitated by rea	ding over a diffuse lig	tht source."	'	included in 1	meremen
				1	Matachwet N)	41 4
	2. The laborator	y procedure manual f	ailed to		Foll - notion - A	Machinen A.
	include a step-by	y-step procedure for	performing	İ	libeling / les	trained on
	Rh(D) testing Ar	nti-D quality control (C	(U) testing	**	All staff have were	L. L. wal
	including the ide	ntity of positive and r	rming OC	i	to the about the	Junior 1
	controls used, the	ne frequency of perfo on for performing qua	ality control		The It all monton	100 1/11/1
1	testing, instructi	ou to benomina da	ancy Corthol	1	Winder 1 mg. 1.	

Division of	of Health Service Re	gulation			" CONDIDUCTION	(X3) DATE SURVEY
STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIDENTIFICATION N			LE CONSTRUCTION	COMPLETED
AND PLAN	OF CORRECTION	IDENCIFICATION N	OHIDE: L	A. BUILDING).	1 _
						C 07/07/2012
*		110748		B. WING		07/02/2013
NAME OF P	ROVIDER OR SUPPLIER		STREET ADD	RESS, CITY	, STATE, ZIP CODE	
	·		400-B CRI	UTCHFIEL	D ST	
THE BAK	ER CLINIC FOR WO	MEN	DURHAM,	NC 27704	·	
	SUMMARY ST	ATEMENT OF DEFICIENC	IES	ID	PROVIDER'S PLAN OF C	CORRECTION (X5)
(X4) ID PREFIX	(EACH DEFICIENC	Y MUST BE PRECEDED !	BY FULL !	PREFIX	(EACH CORRECTIVE ACTI CROSS-REFERENCED TO T	HE APPROPRIATE DATE
TAG	REGULATORY OR	LSC IDENTIFYING INFOR	MATION)	TAG	DEFICIENC	7)
					In I a There has	nbeen 10 2/0/13
E 154	Continued From p	age 5		E 154	compliant harm to sa	thents 1
	1	-	OC and the		a market	RA lookbuch
	testing, now to inte	erpret the results of take if the QC res	ulte are	:	Indenied through	1 1
) take ii the QC res	ulio arc		1. I & proficer	a ferling sques
	unacceptable.			Ì	aleas and from	chtablishing a
	3 The laboratory	procedure manual f	ailed to	1	The laboratory to	Chitagray on
	include a step-by-	step procedure for t	using the	}	rolicy for test	· Op o
	ALBAcheck - BGS	Reagent Control for	or Anti-D.		le of festin	J. Previously
				4	teach and to	Rho and
	4. The laboratory	procedure manual f	failed to	}	Jested Rocumenters	l las
	include a procedu	re describing the co	ourse of	j	tested kocumented	ve men
	action to take if th	e Rh(D) testing was	s unable to	1	Pho No and	necounty
	be performed (e.g	j. no Anti-D availabl	le, no quality		en blood will controls of fested control fe	0.00 mill
	control material a	vailable, quality con	itroi resuits		to to l'antrol de	acell of a
	unacceptable).			i	fested control le be kept at Cline	in latons
	- m	secondura manual	failed to	<u>i</u>	be kept at Cline available for see and control log combined into or	1) Ressent
	5. The laboratory	procedure manual step procedure for	nerforming	ļ	Ille for ser	eus. P
	include a step by	collection including	the		avanova 10 0 ma	5 Love been
	laboratory's redui	rements for labeling	n the	Ì	and Control to	1 m Kalenlatel
	specimen, if appl	icable	5	1	l'alinto o	e constant
	specimen, il appi	ioabio.			low to arme	on slete
	B. The ALBAcion	ne Anti-D blend pro	duct insert		log to arme	at 1 +R
	(Z041UQPI/02 J	une 2010) RECOMI	MENDED	}	documentation (Allachment 2)
	TECHNIQUES s	tates "Slide Technic	queAdd 1	İ	documental	V. tannel
	drop of blood gro	ouping reagent to ar	1		100 Stall have	been 1
	appropriately pre	pared area of a gla	ss slide e.g. a	a	All staff have	and and
	wax pencil oval.	Add 1 volume of re	ed blood cells		on how to full	1 11 touting
	suspended to 30	-45% in group hom	lologous		+ Patien	I The lessy
	plasma/serum.	Mix well by rocking	the slide lot		actument	# RGS
	approximately 30	seconds and incul	ith occasions	1	1 Dh wastrol 4es	17, 100 4
		18-24 degrees C w	RIT VOUGSIVEIG	* }	17	- Pregunene 15
	mixing"			1	VAIBAchech) con	my 1 1 amen
	The laboratory n	rocedure titled "Lat	Procedures	n }	A rateent	Jested Brille
	etates "1 Recor	d refrigerator and re	oom		for even	Il lests and
	temperature in t	he lab 2. Bring reag	ents to room	.	I fest in for a	if I tellar
	temperature (20	*-30*) Rh testing:	Mix 1 drop	į	11+10000	The Hers To
	blood and 1 dro	p of Anti-D Reagent	t on slide, roc	k i	What To sur]	1 (see all 1
	gently (mix) for	30 seconds; incuba	te (observe)	3	for any reason	(4) M. o ohn
	for 5 minutes at	Room temp if need	ied"		previous Attacker	ems) . Inc ////

Division of	of Health Service Re	egulation		0(0) 10 0 710	LE CONSTRUCTION .	(X3) DATE SURVEY
STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLII IDENTIFICATION NU	ER/CLIA	-		COMPLETED
AND PLAN	OF CORRECTION	IDENTIFICATION NO	************	A. BUILDING	3:	
				12		07/02/2013
		110748		B. WING		1 07/02/2013
NAME OF P	ROVIDER OR SUPPLIER		STREET ADI	DRESS, CITY,	STATE, ZIP CODE	
			400-B CR	UTCHFIEL	DST	
THE BAK	ER CLINIC FOR WO	MEN	DURHAM,	NC 27704	}	
		THE STATE OF SECIOISMO	<u> </u>	. di	PROVIDER'S PLAN OF CO	RRECTION (X5)
(X4) ID	ARACH DEELCIENC	ATEMENT OF DEFICIENCE Y MUST BE PRECEDED B	Y FULL	PREFIX	(FACH CORRECTIVE ACTIO	N SHOULD BE COMPLETE
PREFIX TAG	REGULATORY OR I	LSC IDENTIFYING INFORM	ATION)	TAG	CROSS-REFERENCED TO THE DEFICIENCY)	- M. L. KOLI WALE
,,,,				<u> </u>	1 1	the travel alata
T 454	Continued From D	ane 6		E 154	technist cowsultan	1 ms 100 H
E 154	Continued From page	aye o		4 1 1	all Lesting resson.	elimall the
		5			Frise A	ince-E)
	The laboratory's ro	oom temperature rar	ige of 20 to		above (see 44)	
	30 degrees C (Cel	Isius) was observed	to be	ĺ	and lacets of the pr	oceane wit
	outside the manuf	acturer's specification	ns of 18-24	i	the O. O. At stale	including
	degrees C for perf	forming Rh(D) testin	g using	į	reviewed with 19	4
	ALBAclone Anti-D).			none wolumes and	James of
		A st To blood was	duct inport		The The	Lechning
	C.1. The ALBACK	one Anti-D blend pro	ALITY	₹ -	the procedure the	witor gel
	(Z0410QPI/02 Ju	ne 2010) states "QU lity control of reagen	ALII I		soughted will mo	
	CONTROL Qual	uld be performed wi	th each		to lo complex	and . (mile)
	essential and sho	oups, single RhD gro	ups and in	•	systems o	at have
	accordance with	local, state and feder	ral		is been No appear	Al Jones NOW
	regulations Wes	suggest that the follo	wing red	Ĭ	tents I the	la voice of the
	blood cell sample	es are used to contro	l the		As broken	and wegether
	reactions of this r	eagent. Other red bl	ood cell		Lests a positive	+ Pm
	types may be suit	table but should be s	selected with	n [J-cell 6	low to
	care.				Know lead	to patient
				Ì	Know her mior	
	O R1r red blood	ceils should be used	as a		lach . Attac	hme ()
	positive control	•		i i	Jestin (see	
		ells should be used a	s a negative	•	E Desd pm	ode
	control"				miles	Dh Timpe
1		4 17152 125	D-+divent	,	mevousty territor	
	The laboratory p	rocedure titled "Lab	Procedures		l'e l'ele	n (ab)
	does not indicate	e quality control testi	ny usiny dicell contro	1	(results on file.	(A) ord (D)
	positive and neg	ative Rh(D) red bloo ed each day patient f	th(D) testing	71	To wed an a	
		d each day pagent i	(11(2) 100111	9	1 1 th Volore	& being
	is performed.			}	control wind	and early and
	Review of labora	atory testing logs from	n January	1	10 malin EDIA	half lather
	16 2013 through	h July 1, 2013, revea	led the	ļ	for I have san	Luzea War
	laboratory perform	rmed and reported F	th(D) testing]	labeled The	they late.
	results on 108 p	atients when no qua	lity control		H. 14-day LAPIN	1000
	testing was perf	ormed (see D5449).		1	The state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the s	I blood and
					Records of form	e Cal and
	2. The ALBAche	eck - BGS Reagent (Control for	1	maintained in clin	we know
	Anti-D product	nsert (Z271UQPI/01	05 October	Ì	The Coll Land	view. 17 New / /
,	2009) states "IN	TRODUCTIONTh	is reagent is	\$	available The sol	ue hos been 9/17/1
	designed to be	used as a negative o	control in	ţ	Rh Torong Modell	1/11/1

	of Health Service Re	egulation		Octobra Maria Tipi	CONCTRUCTION	(X3) DATE SURVEY
	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLII IDENTIFICATION NL	INTERPORT		E CONSTRUCTION	COMPLETED
AND PLAN	OF CORRECTION	IDERTIC IOMIONIAC		A BUILDING		
				O MINN O		C 07/02/2013
		110748	<u>, </u>	B. WING		1 01/02/2013
NAME OF P	ROVIDER OR SUPPLIER	•	1		STATE, ZIP CODE	1
	יבה כן אווס בסס שים	BASSA	400-B CR	JTCHFIELI) ST	
THE BAK	ER CLINIC FOR WO	MEN	DURHAM,	NC 27704		
(X4) ID	SUMMARY STA	ATEMENT OF DEFICIENCI	ES	ID	PROVIDER'S PLAN OF	CORRECTION (X5)
PREFIX	(EACH DEFICIENC)	Y MUST BE PRECEDED B'	Y FULL	PREFIX TAG	(EACH CORRECTIVE AC CROSS-REFERENCED TO	
TAG	REGULATORY OR I	LSC IDENTIFYING INFORM	IATION)	PAG	DEFICIEN	
				*	la la Tel which	seguies a 7/12/13
E 154	Continued From pa	age 7		E 154	in the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of th	1) Le sun
	conjunction with th	e following Anti-D pr	oducts:		(f) and Cow!	LOC TO VI
	703111 703611 70	39U, Z041UINTE	NDED		a 10 dest	ent festing
	PURPOSE ALBA	check - BGS Reage	nt Control		fren day	All staff have
	for Anti-D is intend	led for use as a neg	ative		(Attachment).	
	control in conjunct	ion with Alba Bioscie	ence		The trained le	gardy the older
	monoclonal Anti-D	reagentsINTERP	RETATION	ì	Deen los	ne control
	OF RESULTS If a	a positive result is ob	tained with	į	Rh Typing Pro	of! and
	ALBAcheck - BGS	Reagent Control fo	r Anti-D	1	frequency and the	Man Ofz
	this will invalidate	the test result obtain	ed with the		It sustation of	all results
	respective ALBA	Bioscience monoclor	nai Anti-D	1	may a delate	BGS reagent
	reagent and the re	ed plood cells.		1	AN ALBACAN	run with
	The laboratory bo	d no documentation	of running	1	trol will be.	Man 100
	the ALBAcheck	BGS Reagent Contr	of for Anti-D		for the	ted. This is
	with each of the 1	08 patient Rh(D) tes	ts		lach foller the	DI turning
	nerformed since t	the facility opened or	January		included in the	Steff have
	16, 2013	are realist of the	•	t 1	grevall procedure	2. 8170
					destate to	
	3. The ALBAclone	e Anti-D blend produ	ct insert	1	blen Trainer	well (a)
	(Z041UQPI/02 Ju	ine 2010) states "Te	st	İ	BGS results a	O Demond
	Procedures Gen	eral Information Thi	s reagent	ŀ	1 -u contra	of and which
	has been standar	rdised for use by the	techniques		negative	be involed.
	described below	and therefore its suit	apility for	ţ	when a fest man	8 Oliveral en
	use in other tech	niques cannot be gu equired to be incubat	aranteeu. od for a		1 Jents	and in the second
	oposifications peri	iod, a timer should b	e cu ioi u	ļ	when a test man	(meliden) M
	usedSlide Tech		of blood		Procedure to the	on results
	grouping reagent	t to an appropriately		ĺ	procedure action	N Dear
1	area of a class s	lideAdd 1 drop of r	ed blood		A time	1 hos vien
	cells suspended	to 30-45% in group	homologous		Italy to en	more!
	plasma/serum.	Mix well by rocking t	he slide for		Jotamed To	2.1.
	approximately 30) seconds and incub	ate the test	. โ	timing (incut	ntcon)
	for 5 minutes at	18-24 degrees C wit	h occasiona		Timenz Coxx	- Il have been
	mixing. After inc	cubation, immediatel	y observe	<u> </u>	Rh Jesting ,	700 1 1
	macroscopically	for agglutination".			inserviced on	proper technique
		. 1-1	vimataki	1.	inserviced on	of the fest
	While touring the	e laboratory at appro	there was a	10	I testing time	y of the first
	9:10AM, the sul	rveyor observed that	ulcic Was II setina sres		9 01 1	hing of stoiles,
	The director stot	the counter in the to ted that they look at	the wall cloc	k İ	mixing and loc	10 /19/11
1	i me unector star	tou that they look at	MIC WALL CIOC		1' 0	

	of Health Service Re	egulation		Ores Adul TIDI	FOONETBUCTION	(X3) DATE SURVEY
	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIDENTIFICATION N	IER/CLIA		LE CONSTRUCTION	COMPLETED
AND PLAN (OF CORRECTION	IOCIATION CONTOUR		A. BUILDING	*	
						C
		110748		B. WING		07/02/2013
NAME OF PE	ROVIDER OR SUPPLIER		STREET AD	DRESS, CITY,	STATE, ZIP CODE	
				UTCHFIELI		
THE BAK	ER CLINIC FOR WO	MEN	DURHAM	, NC 27704	-	
200	SHAMARYST	ATEMENT OF DEFICIENC	CIES	ID.	PROVIDER'S PLAN OF	CORRECTION (X5)
(X4) ID PREFIX	/EACH DEFICIENC	Y MUST BE PRECEDED I	BY FULL	PREFIX	(EACH CORRECTIVE ACT CROSS-REFERENCED TO T	ION SHOULD BE COMPLETE DATE
TAG	REGULATORY OR	LSC IDENTIFYING INFOR	MATON)	TAG	DEFICIENC	Υ)
			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	<u> </u>	1 6 1 G 20 2 G	> red-all 7/17/13
E 154	Continued From p	age 8		E 154	are of a mine	171.
	•	-	e started	4	Konthols, and use	-80 th f 0
	to see what time u	ne Rh(D) testing wa leck the clock for 5	is started minutes: He	-	NRA lock -BG-Sle	agent control o
	and continue to cr	the interview that o	nly one	1	The state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the s	I wonto
	patient is in the lat	oratory at a fime	iny one		Technical Conque	1 an sotema
	patient is in the idi	Jordion y die de linner	Ÿ	1	compleance Mount	a company
	During an observa	ation between 11:30	AM and		Intra and QASI	udies to ensure
	11:40AM. the sur	veyor observed Rh	(D) testing		tening to	There appears
	being performed	on a patient. Testing	personnel	İ	accended testing	0 1/4
	(TP) #2 began the	Rh(D) testing by p	lacing a		In la 10 asparent &	and one
	drop of ALBAcion	e Anti-D blend bloo	d grouping	- Artista	to the serve	It of faither
	reagent on one si	de of the slide and	a drop of the	·	patients	a QCon
	ALBAcheck - BG	S Reagent Control f	or Anti-D on		to test Ward.	+ L readestal
	the other side of t	he glass slide. She	then placed		and down that for	land line
	a drop of the patie	ent's blood on top o	r the		each a tou	se the Albrichen
	reagents on each	side of the slide, ro	ocked the		and faither	A las times
	slide back and to	rth a few times to m	iix liie ieu ihan walkad		SGS reagent con	March 1
	blood cells and the	e reagents. TP #2 ter in the lab and pla	aced the	į	J. Deviced	by centers of
	Homooyo bemon	lobin cuvette in the	Hemocue	•	There is the	1 auditard
	analyzer to he tes	sted and asked TP	#1 to check		H QA Cook One	Jost in
	on the Rh(D) test	ing while she broug	ht the patier	ıt (or Wot profuse	rey . The 8
	into another roon	n. The timer was no	t used to		greeten to ref	letting accuracy
	ensure the Rh(D)	testing incubated t	for 5 minutes	} }	Scores, Chit	(+F)
	before the result	was determined.		į	d Lesting (Mucho	new P O H.
				i	10 11 10 71" Do	currents letter
	In summary, the	cumulative effect of	f these	}	Attachment 1	1 fler
	systemic problem	ns resulted in the la	boratory's	\ .	Attachment to satisfied to satisfied to satisfied to satisfied with	nto of the
	inability to ensure	e the accuracy and	reliability of		august !	2 splanation -
	patient Rh(D) tes	sting results. There	tore, it is the		re-yening wo	~ 1
	finding of this ag	ency that the facility	neglecteu t		F 0	
		ces to assure the h	cami, saicty			a deline
	and welfare of th	e chents.			p AA A	+ RO.
			0	E 455	A New Guality As har been in plema G). The plan will menual completed records, required	enment pean
E 16	.0309(D) LABOF	RATORY SERVICE	5	E 155	1 Moma	ted CANOCK
					no ven my	I mon to nocedure
	10A-14E .0309 (d) The facility shall			G). The plan will	Jeno.
	perform and doc	cument, at least			manuel amolites	fess, from ry
	quarterly, callora	ation of equipment		1	The reduced	performance of
į.	and validation of	i rest lesuirs.		1	Meroras, 10	1 1 1/1(//

Division of	of Health Service Re	egulation				(X3) DATE SURVEY
STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLI			CONSTRUCTION	COMPLETED
AND PLAN	OF CORRECTION	IDENTIFICATION N	JWIDET.	A BUILDING:		
						C
		110748		B. WING		07/02/2013
NAME OF PI	ROVIDER OR SUPPLIER		STREET ADI	DRESS, CITY, S	STATE, ZIP CODE	
		u. n. i-n. i. 8	400-B CR	UTCHFIELD	ST	
THE BAK	ER CLINIC FOR WO	MEN	DURHAM,	NC 27704		
1	OI SEANADY OT	ATEMENT OF DEFICIENCE	FS	ID	PROVIDER'S PLAN OF CORRE	CTION (X5)
(X4) ID PREFIX	(FACH DEFICIENC)	Y MUST BE PRECEDED B	Y FULL	PREFIX	(EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP	OULD BE COMPLETE DATE DATE
TAG	REGULATORY OR I	SC IDENTIFYING INFORM	MATION)	TAG	DEFICIENCY)	ROFKIAL
1					1	100 m 2/11/12
E 155	Continued From pa	age 9		E 155	Specifications, controls	5771110
	-				O. sol policed testing,	reagent
	This Rule is not m	et as evidenced by:	u of	1	the sends excit	ownetenery
i	Based on review o	f test records; review	M OI ence of	į	Control Men 1100	tt. AA
	manutacturers pro	oduct insert; the abs	dure review.	į	festing is included a	a me Cil
	documentation on	July 2, 2013, proceed (D) testing logs; inte	aute teview, aview with	1	10 mm town to	assure !
	review of 2013 RII	(TP); observation; re	wiew of	1	plan money	in cultation
	lesting personner	logs, and review of	2013 lah		some technique and	1. +1.
	loce the facility's l	aboratory staff failed	to verify	<u> </u>	1 + 1 M testing.	, conecure
	the manufacturer's	s performance spec	ifications for	1	time for the	ten failure,
	the M RAcione An	nti-D blend blood gro	upina		action for any 34	200
	readent before ne	rforming patient test	ing: failed	1	to blem etcar	vill be
-	to test a positive a	and negative red blo	od cell		testing protours	Procentrat
	control at least on	ce each day Rh(D)	testing was		trolly technical	an must
	performed: failed	to perform and docu	ıment	4.	monitory 1	Stant
	corrective action (on 15 days between	January 16,	.]	Monthly technical con.	
	2013 through July	1, 2013 when room	}	!	1 Minorator St	off complement
	temperature was	outside the manufac	cturer's	Ļ	visits will	40/
:	specifications for	performing Rh(D) to	sting using	į	in all me-analytic	21) 1 4 9
	ALBAcione Anti-E	blend blood groupi	ng reagent;	ĺ	not not	- analy the
	and failed to esta	blish and follow writt	en policies	}	analytical, the	He
	and procedures to	o monitor, assess, a	nd correct	}	processer will and	out of the
	identified problem	ns in the analytic sys	item.		to at solometted to	s let decented
				Market As June	report such	All Lesting
	Findings include:			Ì	after each unit,	
			-4 - 3 #\$	again and an an an an an an an an an an an an an	of counted have trad	can
	A. Review of 201	13 laboratory patient	testing		The state of	w QA
	records showed	the laboratory begar	n performing		enservice of the	184
	Rh(D) testing on	patients using ALBA	Acione Anti-i	J	100 Ree nevrous	AN och mens)
-		ping reagent on JAr	luary 16,		personal have lind inservice on the all Plan (See previous) (See E 154)	
	2013.					į
	The Al DA-teu-	Anti D bland aradisa	t incort		t-0= F154)	
	I Ne ALBAcione	Anti-D blend product	DECIEIC	į	(See L 131)	
	DEDECIDADA NO	une 2010) states "SI E CHARACTERISTI	CS Prior to	}		
	reference cook lot	of ALBAcione Anti-	D blend is	· ·		
	tested by EDA re	commended metho	ds anainst s	ı Î		
	nanel of antigen	-positive and antiger	n-negative			
	red blood cells to	positive and antiger o ensure sultable rea	ectivity."	*	S	1
	Led Nicon cells fo	J CHOUSE GUILDING FOR		i		161-1
	The facility failed	to have documenta	ation availab	le		17/17/
1	() () () () () () () () () ()			3	I .	

Division (of Health Service Re	egulation				(X3) DATE SURVEY
STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIE		• •	CONSTRUCTION	COMPLETED
AND PLAN	OF CORRECTION	IDENTIFICATION NO		A. BUILDING: _		
				B. WING		07/02/2013
		110748	1 155		TATE TIP CODE	07/02/2010
NAME OF P	ROVIDER OR SUPPLIER		1		TATE, ZIP CODE	
THE BAK	ER CLINIC FOR WO	MEN		NC 27704		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIE (EACH DEFICIENCY MUST BE PRECEDED BY REGULATORY OR LSC IDENTIFYING INFORM		/FULL	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE COMPLETE
E 155	Continued From pa	age 10	······································	Ė 155		7/17/18
	documented testin Rh(D) negative inc were able to obtain and negative, whe laboratory. During interview a laboratory director	oratory had performeng of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy of known Rh(D) policy	ositive and rate they as, positive in their 5AM., the deach			
	practice and starte stated during the document any of		le also d not	e de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de la companya de l	(see E 154)	
	(Z041UQPI/02 Ju CONTROL Qua essential and sho series of RhD gro accordance with regulations. We s blood cell sample reactions of this	ne Anti-D blend produ ine 2010) states "QU lity control of reagent buld be performed with bups, single RhD grod local, state and feder suggest that the follow es are used to contro reagent. Other red ble table but should be s	ALITY ts is th each ups and in ral wing red i the ood cell		See L'131)	
	positive control	cells should be used		er, er, er, er, er, er, er, er, er, er,		
	does not indicate	rocedure titled "Lab I e quality control testir ative Rh(D) red blood ed each day patient R	ng using d cell contro			
	Rh(D) testing re	Lab Log" used for do sults includes an are form for documentin	a on the top	And the second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second second s		7/17/r

	of Health Service Re	egulation		(VA) And Time M.	CONSTRUCTION	(X3) DATE SURVEY
STATEMEN	ATEMENT OF DEFICIENCIES D PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		ER/CLIA IMBER:	• •	CONSTRUCTION	COMPLETED
AND PLAN (OF CORRECTION	IDEATH IONION		A. BUILDING:		c
				B. WING		07/02/2013
		110748	I ornere and		ATE ZIP CODE	1 01/02/2010
NAME OF P	ROVIDER OR SUPPLIER		E .	ORESS, CITY, ST		
THE BAK	ER CLINIC FOR WO	DMEN	400-B CR DURHAM,	NC 27704	-	
(X4) ID PREFIX TAG	/EACH DEFICIENC	ATEMENT OF DEFICIENCE Y MUST BE PRECEDED B' LSC IDENTIFYING INFORM	Y FULL	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOT CROSS-REFERENCED TO THE APPROPRIEMENCY)	OULD BE COMPLETE
E 155	Continued From p	age 11		E 155		7/17/13
	(positive) Control a	and Rh- (negative) C	ontrol lot	100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L 100 L		
	number, expiration	i dale alla lesuit.				
	Review of the "Lal	b Log" from January	1, 2013	1	500 H 1541	***************************************
	through July 13, 2	013, revealed the la	boratory		See E 154)	i â
	documented only	the results of an Rh- on 1/16/13, 2/20/13,	CONTROL 3/6/13	\		
l	result of negative	and 5/20/13, 2/20/13, and 5/20/13,	eparate			
	"I ab Log" the labo	oratory documented	positive and			
·	negative control re	esults for the ALBAC	ione Anti- D		•	
	blend reagent on	6/2/13 and 7/1/13.		* Approximately		
		at approximataly 10:4	TO MACE	,		1
	During interview a	at approximately 10:the tested the control	s on July 1.	7-6-6-1		
	2013 she had a p	ositive and negative	result. She			
	stated she used a	a drop from each bot	tie of			
	ALBAcheck Read	gent Control and add	led a drop o	f		
	ALBAcione Anti-I	ond had a positive	result on	·		
	one slide and a n	negative result on the	Outer Singe.			
	Between 10:50Al	M and 11:10AM, the	surveyor			
	observed testing	personnel (TP) #1 p	erforming			
	positive and neg	ative quality control t	esting using			
	the ALBAcione A	nti-D blend blood gr	ouping	1		4
	reagent and the	ALBAcheck - BGS R	ceageni one of of the	, j		
	Control for Anti-L	D. TP #1 placed 2 dr SS Reagent Control o	ops of or the on 2 class			Ì
	slides and add 2	drops of ALBAcione	Anti-D	į.		
	blend blood grou	iping reagent to eacl	n glass slide	. 1		**
	She then rocked	I the slide to mix the	2 clear	1		i I
	reagents togethe	er. After approximate	ely 5 minutes	\$		1
ļ	there was no vis	sible reaction on eithe	er siide.	1	See E154)	
	Paviow of labora	atory testing logs from	m January		KOR EISTI	
	16, 2013 through	h July 1, 2013, revea	aled the	1		
	laboratory perfo	rmed and reported F	th (D) testing	9		
	results on 108 p	atients when no qua	lity control	1		
	testing was perf	formed.		1		1
	C The ALBACI	one Anti-D blend pro	duct insert			17/17/
1	U. THE ALDACI	OHE WHILD DIGHT BLO	add Hoost	1	!	

STATEMEN	T OF DEFICIENCIES	(X1) PROVIDER/SUPPLIE	R/CLIA	(X2) MULTIPLE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
AND PLAN	OF CORRECTION	IDENTIFICATION NU	IMBEK:	A. BUILDING:		_	1
		110748		B. WING		07/02/2013	3
NAME OF P	ROVIDER OR SUPPLIER	I	1 '		STATE, ZIP CODE		
	ER CLINIC FOR WO	MEN		UTCHFIELD , NC 27704) ST		
(X4) ID PREFIX TAG	(FACH DEFICIENC	ATEMENT OF DEFICIENCIE Y MUST BE PRECEDED BY LSC IDENTIFYING INFORM	FULL	ID PREFIX • TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SI CROSS-REFERENCED TO THE AF DEFICIENCY)	HOULD BE COMP	LETE
E 155	TECHNIQUES stated appropriately preparately preparately preparately preparately preparately appropriately preparately 30 for 5 minutes at 15 mixing" Review of temperately 30 for 5 minutes at 15 mixing" Review of temperately 30 for 5 minutes at 15 mixing" Review of temperately 30 for 5 minutes at 15 mixing" Review of temperately 30 for 5 minutes at 15 mixing" Review of temperately 30 for 5 minutes at 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for 15 for	ne 2010) RECOMME ties "Slide Technique ping reagent to an ared area of a glass add 1 drop of red blood \$5% in group homolo ix well by rocking the seconds and incubat 8-24 degrees C with ature logs from Janu 13 revealed room tel vas documented as 2 of 137 days (1/14/13 5/2/13, 5/10/13, 5/11 6/7/13, 6/8/13, 6/13/- i/13. ab Log" from January 013 revealed Rh(D) to esults reported on 16 erature was outside to pecifications for testif 5/18/13, 6/7/13, 6/8/ and 6/18/13). alled to have docume to taken corrective acc then the temperature 25 degrees C and pa	slide e.g. a od cells and cells agous e slide for the test occasional arry 4, 2013 amperature 25 degrees 3, 3/2/13, /13, 6/14/13 esting was patients the ng (3/2/13, 13, 6/13/13 antation tion for any was tient Rh(D) itten quality ion of the aluating and		The laboratory has imparted to consect testing tensor the laily lab lasting testing the person the daily lab lasting sure the resonanced on the making sure the sure for the most at of tensor sange (18) Steff instructed to the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tensor the most at of tenso	a along	13
	1	e manual failed to inc	clude	Approximation : a pro-payage	to many lev	el, and 71	17

Division o	of Health Service Re	equiation				(X3) DATE SURVEY
	TAT LIVELY OF DELI DICTOR			, ,	E CONSTRUCTION	COMPLETED
ANU PLAN (OF CORRECTION	INCIALIZATION IND		A. BUILDING:		
				B, WING		07/02/2013
		110748	OWNETT AN		STATE, ZIP CODE	OTIOZIZONO
NAME OF P	ROVIDER OR SUPPLIER			UTCHFIELD		
THE BAK	ER CLINIC FOR WO		DURHAM	NC 27704		
(X4) ID PREFIX TAG	(FACH DEFICIENC)	ATEMENT OF DEFICIENCIE Y MUST BE PRECEDED BY SC IDENTIFYING INFORMA	FULL	ID PREFIX TAG	PROVIDER'S PLAN OF CORRI (EACH CORRECTIVE ACTION SI CROSS-REFERENCED TO THE AP DEFICIENCY)	HOULD BE COMPLETE
	testing 2. The laboratory's not within manufact performing Rh(D) for a superforming Rh(D) for a superforming Rh(D) for a superforming Rh(D) testing.	ailed to verify the rformance specificati failed to test positive	ange was for ons for the	7	lookbach audit in the 16 patients testy on the the room teng was ronge (25°c). See attachment). There I	previous previous her been patients
	of patient testing, reagent control wi failed to follow the incubation of Rh(I). 5. The laboratory action when room manufacturer's sp. Rh(D) testing. In summary, the control systemic problem inability to ensure patient Rh(D) testing of this age.	failed to perform corrected temperature was out becifications for performant temperature effect of the resulted in the laboration accuracy and reting results. Thereforency that the facility roes to assure the hear	h(D) I, and uctions for ective tside the rming nese oratory's liability of re, it is the neglected to		As a result of fails assure moper tests Frech. consultant win for compleance. Etc reficiency testing (100% accuracy) of accuracy and relia festing. 500 E154 fo	l monton allent seores lest billy of
				ماند الله المرسومين	:	7/17/1

pto1 pts/10/13/11/13

<u>Lab Log</u> The Baker Clinic For Women IHE, 0309

108 dars 33

	14E,03	107 L	ot#E	xp. Date	Result	
	*	-Rh+ Control:	202	1,,,,	u C	1/26/13
DOD	Data	ÁΙ	LBA Ch	eck (Quot	ient)	Tech
7 7	, ,	F Hot#/Exp date			Kn ⁺	DHB
	, ,					٠,
						Jr JHB
						EH PW
4-6-88	2-1-13			12.6		<u> </u>
6-5-89	2-1-13			11. le	(+)	aer
8-22-84	2-4-13			11.9	(+)	aern
6.23.90	2.9.13		_	14.6	(+)	EHPW
			_	12.1	(alen
5-31-94	2.12.13			13.5	Ŧ	Jh.
	2-15-13		_	11	(CA,
		_	_	9:6	+	CH
				13.6	\oplus	ae
9.22.49	2.16.13		_	10.6	D	Eypu
1.			-	11.1	+	C Kel
		_	_	13.2	(E)	C Kee
-13-88	2-16-13			11.1	\oplus	C Kel
5-14-92	2-18-13		-	15.1		alfn
		04042815 CK	(A)	13.6		EXPM
7,13,83	12.2.1.2	26p. C-1/14			CON/201	
					1/0/17	X DAIS
					2(20) 131	
5 04/14		★ "Anti-D Blend" "ALBA clone"				
1 1 1		(Quotient) Lot #: V(17718				
	8-22-84 6.23.90 02-01-91 5-31-94 12-5-88 9-27-84 7-10-80 9.22-99 4-21-89 2.33.90 1-13-88 5-14-92 2.13.85	DOB Date 8/30/83 1/16/13 511/1971 1/16/13 7.17.93 1.30.13 4-6-89 2-1-13 6-5-89 2-1-13 6-23.90 2.9.13 02-01-91 2-11-13 5-31-94 2.12-13 12-5-88 2-15-13 9-22-84 2-15-13 9-22-84 2-15-13 9-23-90 2.16-13 4-21-89 2.16-13 2-38-90 2.16.13 5-14-92 2-18-13 2.13.85 2.12-13	Rh+ Control: WIA Rh- Control: WIA Rh- Control: WIA AI DOB Date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date * PTlot#/Exp date *	Rh+ Control: (**)4242	Rh+ Control: W1923	Rh+ Control: W1923 1/2/H Rh- Control: W1923 1/2/H ALBA Check (Quotient) Rh+ PTlot#/Exp date PT Hgb* Rh* 8/30/83 1/14/13 — 1/2

Courte): 123, ±0.3 2/20/23x

Lab Log The Baker Clinic For Women

IHE,0309

Lot # Exp. Date Result

(10)		a a	Rh+ Control: Vila	230 1-1	0-14 u (V3/altrs
	DOB	Date	AI * PTlot#/Exp date	LBA Che	ck (Quoti Hgb*	ent) Rh*	Tech
Name	9-20-93			<u></u>	13, 2	NII -	alen
	5.14.92	22313			11.3 a/dl	NA	EYRN
	11.12.81	2,27.15		_	13.5yd	' 1	Eyrn
	7-14-94	3-1-13	-	_	13.2	Ð	al RN
	7-31-81	3-1-13			10.9	(F)	alry
	8-11-92	3.2.13		_	13.0gk	\oplus	eym)
Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Company of the Compan	7.31.95	3.4.13		_	13.4	(+)	EYKN
	11-2-89			_	13.6	1	alrn
	3-2-92		:	_	12.2	Ð	ackn
	1-13-94				11.3	\bigcirc	alkn
	3.14.93	3.16.13	_		11,8	(H)	Zypi-
	4-5.92	}	_	_	13.9	(+)	CK
	01-09-95		33		12.1		CK
145	11-14-92			_	13.3		CK
		4-3-2013			12	(+)	C.K
	2-3-87	4-3.20			11.6	\bigcirc	CK
	7-11-88	4-5-201	_		11,5	(CR
	3 29.91	4-6.20		>	13.6		CK
	9 11	+	 				

*HCG dipstick ("1-Step Cassette")

L Medical, Supplier

** rigb Control: (Lot #/Exp Date)

"Photometer" (Control Cuvette): 12 3 ± 0 3 4/6/13 (14)

"Total System" (RDS Systems):

-18.88 4-10-2013

#: <u>V117718</u> Exp. Date: <u>11/23/13</u>

<u>Lab Log</u> The Baker Clinic For Women

14E,0309

Date: 4-14/15/2013 - 5	186013	116,00	Rh+ Control:	<u>Lot #</u> <u>E</u>	xp. Date	Result	
			Rh- Control: V	119230 1	-10-64	"E"4	15/13/01/15
Name (D)	DOB	Date	* PTlot#/Exp date	ALBA Che PT	eck (Quot Hgb*	ient) / Rh*	Tech
2	4-10-86	4-15-2013			12.6	B	C Kalo
Uni	2-6-99	4.19-201			8.0	\mathcal{F}	V. Lee FN
	9-24-84	4-20-20	113		11.3		2 4 200
	9-16	4-20-20	13		11		C Yell
	2-5-85	4-22-13			12.8		C Leet 2
	10-1-81	4-22-13			11.1	1 \	C. Kell
	i- ZZ-85	4-24-13			11.2	1 1	C Kell
	12/970			(3)			C Kel
	8-12.83	4-27-13			13 7		2 Kally
	4-27-79	5-4-13			11.9		C Kalli
	1/4/1981	 			15.5		C Kele
	10/28/86	5-6-13			12.5	(+)	C Kels
	1/5/93	5-8-13	ì		. 11	1	C Koll
	8/23/77				11.1		C Kell
	10/9/91	5-8-13			11.7	D	Kobert
	5/8/85	5-9-13			12.2	(±) [c Yell
	12/12/94	5.13.13			8.6	£	C Kel
	7/2/23	5-14-13			11.6	+	C Yell
	2-1-93	5-15-13			10.0	(A)	C Xell
	9-20-94				114'2	(A)	C Tes
*HCG dipstick ("1-Step Cassette") Medical, Supplier 04062m6 Medical, Clot #/Exp Date)	1	da (s. s	"ALBA clone"	see con		u/23/13	
"Photometer" (Control Cuvette): 22:	$\frac{5+0.5-5/18}{-}$	113/ JHB_	Lot #: V117718	I	exp. Date:_	4/2/10	

<u>Lab Log</u> The Baker Clinic For Women

14F 1319

	,	14E,03	309 ₁	Lot # Exp. Date	<u>Result</u>
Date: 5/20/2013 - La-6	2013		TO 1 CT 1 1		
(20)			Rh- Control: VII	9230 /10/14 LBA Check (Qua	y 5/20/3/10
Name	DOB	Date	* PTlot#/Exp date	PT Hgb*	Rh* Tech
	5/16/85	5-20-2013		9.8	+ C. Keller
	12/8/6	5-20-13		13.3	D C Keller
	17/12/85	S-20-13		13.1	D. Tuel
	1-11-81	5.24-13		12.7	+ C Kiell
	12.8-90			10.2	D C Kell
	11-18-90	ļ.		/1,5	D C Tool
	7-16.87			10	+ C Kalla
	10-5.87	1		1112	D C Kell
	7-8-87	1 ,		13.4	
	11-16-95	6-1.13		11.a	+ c Tele
	12-25-85	1.		11/1	€ C K.00
	3-21-84			11.7	1 Wasert
	1-8-88	6-4-13		14.1	DC Kalla
	2-8-81			12.0	OC X OO
	5-24-96	1.		10.2	D C Kee
	7-18-93	6-6-13		11.2	C Kele
	2-8-87	6-6-13		10.7	O C Kelle
	10.23.84	6-6-13		11.4	D a Kelle
	4-12-81			9.5	
	10,21-88	6.6-13		12.4	D (Talle
*HCG dipstick ("1-Step Cassette") `. Medical, Supplier gb Control: (Lot #/Exp Date) 5/2 "Photometer" (Control Cuvette): 12 "Total System" (RDS Systems): 5/29/13	11,2 19 13 GH113 13 (+/+03)5 6 11.2	5.6 23°CK 118/13 /CK	* "Anti-D Blend" >> "ALBA clone" (Quotient) Lot #: V\\ 718	Exp. Date:	1

<u>Lab Log</u> The Baker Clinic For Women

14E.0309

	Lot#	Exp. Date	Result
h+ Control:			

Date: 676	013- 6-25/	3		Rh+ Control:	<u>Lot #</u> <u>F</u>	Exp. Date	Result	
	(20)			Rh- Control:	ALBA Ch	aak (Ovat	iamt)	
Name		DOB	Date	* PTlot#/Exp date		Hgb*	Rh*	Tech
		6/30/79	6-7.2013			13.6	(H)	C Kelle
		1-26.94	6-7.20	3		11.1	(H)	C Kase
		3-3-73	6-8-20	3		12.3		C Kalla
		1-8-87	6-10-30	3		10.1	(F)	c Keller
		9-11.87	6-11-20	B		11.8	\bigcirc	C Kagge
	320	12.17.92	6-13.20	p13		13.4	(F)	C Keller
CE DE	5	6-12.76	6-13-2	P13		10.1	1	C Keel
(3)			6.15-20	113		8.2	0	de >1 9
COL.	(18)	9-6-85	6-15-2	B		14.1	D	C Karle
CANC	3(13)	7-18-86	6-15-20	13		12.9	D	2 Kelle
		8-1-84	6-15-2	В		10.8	E	CKell
	CONTRACT OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PARTY OF THE PA	D.26.94	6-15-6	013		13,7	D	C Kalls
The state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the s		8-21-84	6-18-2	013		11,6	D	C Kelle
JEDZ-		10.24-89	6.20-1	3		19.5		C Yell
		1-18.77	6.20-13	3		15.0	9	C Kelle
(COXED)		8.4.94	6-22-13			10.8	D	C Xallo
(S)()	(alas)	8.3.93	6-24-13)		12.3	9	(Keller
93000	O'CORT '	-20-87	6.24-13	}		12.9	(D)	C X sell
GEE	253	6-6-93	6.25-13	×		10,7	D	C Kelle
(a) (a)		4-4-85	6-25-13			11.2	(t)	J. Roberton

*H(CG	dipstic	ck ("1-Step	Cassette	")
	11/12	dical	Cir	polier		

. Medical, Supplier

* _gb Control: (Lot #/Exp Date)

"Photometer" (Control Cuvette):

"Total System" (RDS Systems):

★ "Anti-D Blend"

"ALBA clone"

(Quotient)

Exp. Date: Lot #: ____

<u>Lab Log</u> The Baker Clinic For Women ME.0309

Date: 425/13

Lot# Exp. Date Result

Rh+ Control: Rh- Control:

				ALBA Che			
Name	DOB	Date	* PTlot#/Exp date	PT	Hgb≉	Rh*	Tech
6500	5/20/95	(e 26 /13		in	11.9	D	posent
The Designation of the second	2/2-1/28	6/27/13		Am	13.5	\oplus	lest D
					13.S	(+)	C X OA
T.	,	()					
	6-3-92	6/27/13	>	1.	10.8	E	C. Kee
(A)(a ~ ((D)	1-24.74	6/27/13	3	-	12.4	1	C Kell
The Target	11-22-89	6/28/0	3		12.4	1	e Kall
THE STATE OF	D 9-29-86	6/28/13			10.8	A	C ×eee
0000	3-12-80	6/28/13			١٦	D	C Kale
AT GO SUS	D 12/5/1987	4/24/13			12,3	D	pobert
STORY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE P	MAISA	6 /29/13	3	+			C Kell
STEEL STEEL	5/3/85	6/29/13			11.4	1	C Keel
CE ESTE	9-16-86	7-1-20	13		10.6	0	C (20
**							
· .							
					-		
,						-	

*HCG	dips	tick	("1-Step	Cassette")
			* *	

* "Anti-D Blend" See control lug "ALBA clone"

(Quotient)

Lot #: VII 7718 Exp. Date: 11 23 13

Medical, Supplier

#rigb Control: (Lot #/Exp Date)

"Photometer" (Control Cuvette): 12.3 (± 0.3) 4 25 13 years

"Total System" (RDS Systems):

Lab Log The Baker Clinic For Women

IHE,0309

<u>Lot #</u>	Exp. Date	Result

Date:	

Rh+ Control:

Rh- Control: ALBA Check (Quotient) DOB * PTlot#/Exp date Hgb ★ Date Rh* Tech Name Lot V119230 C Kelli Blend 6213 2014-1-10 Lo+ V119230 CKallu (F) Blend 2014-1-10 Lot V119230 Blend C Kaller 2014-1-10 Lot V119230 Anti O Blend ulle >> 11113 2014-1-10 5.4 Lot Ghlia 7/1/13 Control Cu vet C. Keller 7/1/13 12.3

*HCG dipstick	("1-Step	Cassette")
---------------	----------	------------

. Medical, Supplier

★ rigb Control: (Lot #/Exp Date)

"Photometer" (Control Cuvette): (2.3 ± 0.3 4/11 (7/1/13)
"Total System" (RDS Systems):

₩ "Anti-D Blend"

"ALBA clone"

(Quotient)
Lot #:

Exp. Date: