Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	110748	A. BUILDING: _____ B. WING _____	C 07/02/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE BAKER CLINIC FOR WOMEN	400-B CRUTCHFIELD ST DURHAM, NC 27704

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 000	INITIAL COMMENTS On July 2, 2013, staff with the Acute and Home Care Licensure and Certification Section surveyed The Baker Clinic for Women. The survey findings revealed a potential imminent threat to the health and safety of patients. Based on the survey findings, the facility failed to ensure quality control was performed in blood banking. The facility failed to perform quality control testing on one hundred-eight patients that received Rh(D) testing; failed to ensure the ALBAclone Anti-D blood grouping reagent manufacturer's performance specifications were verified prior to patient testing; failed to ensure a positive and negative red blood cell control material was tested at least once daily when Rh(D) testing was performed; failed to follow manufacturer's instructions for performing Rh(D) testing; failed to define an acceptable room temperature range in accordance with manufacturer's instructions for the performance of Rh(D) testing; and failed to ensure policies and procedures were developed for staff implementation for the performance of patient Rh(D) testing using the ALBAclone Anti-D blood grouping reagent. During the survey at 11:55AM on July 2, 2013, an Immediate Jeopardy was identified in immunohematology and immediately communicated to the physician owner of the facility. The immediate jeopardy was not abated during the onsite survey. Therefore, based on in-office review, it is the finding of this agency that the facility has neglected to provide the services to assure the health, safety and welfare of the clients. As a result of the survey findings, the Section substantiated Rule violations that include:	E 000	The Baker Clinic for Women has taken steps to ensure that there is no potential imminent threat to the health and safety of patients by taking the following steps. A quality control and quality assessment program will be implemented and testing personnel will be trained to follow manufacturer's instructions for performing quality control incubation of Rh typing and for performing testing at the appropriate temperature range. A quality assessment plan has been implemented to identify and correct future problems. The Lab Director has hired a qualified Technical Consultant to assist in providing overall supervision, monitoring and direction for the lab. A quality assessment patient audit of a representative number of the 108 patients tested has been done which reflects NO	7/16/13

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] Baker, MD. TITLE: Laboratory Director (X6) DATE: 7/16/13

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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 (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 000	apparent harm to patients has been done. A letter to the patients has been drafted which explains an issue with testing has been identified and urges the patient to return for repeat testing at no additional charge.	7/17/13
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 failed to ensure laboratory systems were in place to monitor and evaluate the overall quality of testing in the specialty of Immunohematology. Findings include:	E 131	The facility governing authority has taken steps to ensure that laboratory systems are in place to monitor and evaluate the overall quality of testing in Immunohematology (specifically Rh Typing). A complete procedure manual and policy manual have been written for performing Rh testing using ALBAclone Anti-D Reagent (See Attachment A) A revised temperature chart has been put into place with the	7/17/13

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E 131	Continued From page 2 1. The laboratory failed to have a complete and current procedure manual for performing Rh (D) testing using ALBAclone Anti-D blood grouping reagent (see .0309(C)). 2. The laboratory failed to ensure that Rh(D) testing was performed at the temperature specified by the manufacturer (see .0309(C)). 3. The laboratory failed to ensure that the ALBAclone Anti-D blood grouping reagent manufacturer's performance specifications were verified before patient testing was initiated (see .0309(d)). 4. The laboratory failed to ensure that a positive and negative red blood cell control material was tested at least once each day when Rh(D) testing was performed (see .0309(d). 5. The laboratory failed to follow the manufacturer's instructions for performing Rh(D) testing (see .0309(C)). 6. The laboratory failed to perform and document corrective action on 15 days when room temperature was outside the manufacturer's specifications for performing Rh(D) testing. Rh(D) testing was performed and reported on 16 patients on 10 of the 15 days when the room temperature was not within the manufacturer's specifications (see .0309(d)). 7. The laboratory failed to have a quality assessment plan and failed to perform and document quality assessment activities in the general laboratory system, analytic system and post-analytic system to monitor, identify and correct problems in the specialty of Immunohematology (see .0309(d)).	E 131	conect temp. range specified by manufacturer (Attachment B). A performance specification procedure has been written stating any new Anti-D reagent will be approved, tested, and verified appropriately prior to patient testing (Attachment C). A quality control policy has been established to ensure required controls are tested each day of testing (see Attachment D). All testing personal have been trained to follow manufacturer's instructions for performing Rh D testing (Attachment E). Testing personal have been given an inservice regarding corrective action requirement when room temp. is outside limits. The QA lookback audit includes the 16 patients in the sample that were tested when the temp. was outside acceptable limits. (Attachment F). A new quality assessment plan has been implemented which assures QA activities in general, lab	7/17/13 7/17/13

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E 131	Continued From page 3 In summary, the cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient Rh(D) testing results. Therefore, it is the finding of this agency that the facility neglected to provide the services to assure the health, safety and welfare of the clients.	E 131	Systems, analytical systems, and post-analytical systems are monitored to identify and correct problems in immunohematology (Attachment G) A qualified tech. consultant (Attachment H) will assist the lab director in maintaining compliance of procedure manuals, temperature performance specification, QC testing for Rh, performing patient Rh testing, and QA activities. The QA lookback audit of patients tested under inappropriate or adverse conditions reflects that there has been no apparent harm to patients. All staff have been trained on all attachments. Also, proficiency testing scores have been excellent, thus reflecting accuracy of testing.	7/17/13
E 154	.0309(C) LABORATORY SERVICES 10A-14E .0309 (c) The facility shall have instructions for each test procedure performed, including: (1) Sources of reagents, standard and calibration procedures; and (2) Information concerning the basis for the listed "normal" ranges. This Rule is not met as evidenced by: Based on review of the laboratory procedure manual, review of manufacturer's product insert, review of 2013 temperature logs, review of 2013 Rh(D) testing logs, observation and interviews, the laboratory's procedure manual was not complete and current for the testing performed in the laboratory; the laboratory staff failed to define an acceptable room temperature range which was consistent with the manufacturer's instructions for performance of Rh(D) testing; failed to test positive and negative Rh (D) quality control material each day that patients were tested and failed to follow the manufacturer's instructions for performing Rh(D) testing. Findings include: A.1. The laboratory procedure manual failed to include a laboratory specific step-by-step procedure for performance of patient Rh(D)	E 154	A new procedure manual has been written which includes a step by step procedure for patient Rh testing using the ABBAclone Anti-D reagent. The procedure is current. All staff have been trained regarding the new procedure (Attachment E). The technical consultant will monitor compliance of testing. No apparent harm has been done to patients as evidenced	

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E 154	Continued From page 4 testing using the ALBAclone Anti-D blood grouping reagent. The laboratory had a copy of the manufacturer's instructions for use of ALBAclone Anti-D blood grouping reagent, dated 2009, in the laboratory. The laboratory procedure titled "Lab Procedures" states "1. Record refrigerator and room temperature in the lab 2. Bring reagents to room temperature (20*-30*) 3. Run controls and record results as needed/indicated (Lab Log)...6. Perform fingerstick: Hgb testing: fill microcuvette with blood, place in Hemocue, read in 45 secs. (Range 11.0-16.0 grams) Rh testing: Mix 1 drop blood and 1 drop of Anti-D Reagent on slide, rock gently (mix) for 30 seconds; incubate (observe) for 5 minutes at Room temp if needed. (Agglutination = Rh positive, no Agglutination= Rh negative)..." The ALBAclone Anti-D blend product insert (Z041UQPI/02 June 2010) RECOMMENDED TECHNIQUES states "Slide Technique Add 1 drop of blood grouping reagent to an appropriately prepared area of a glass slide e.g. a wax pencil oval. Add 1 drop of red blood cells suspended to 30-45% in group homologous plasma/serum. Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at 18-24 degrees C with occasional mixing. After incubation, immediately observe macroscopically for agglutination. This may be facilitated by reading over a diffuse light source." 2. The laboratory procedure manual failed to include a step-by-step procedure for performing Rh(D) testing Anti-D quality control (QC) testing including the identity of positive and negative controls used, the frequency of performing QC testing, instruction for performing quality control	E 154	through the QA lookback audit. Proficiency testing scores have been accurate and reflect accuracy of testing at the Clinic. The Rh patient testing procedure now contains a quality control section on how to test QC material, what to use, frequency of testing, how to perform the test, how to interpret the testing, and corrective action to take if QC is unacceptable. The procedure also includes a step by step procedure for using the ALBAcheck-BGS reagent control for Anti-D. (Attachment A) The procedure manual now includes a back-up plan if reagents or control material is unavailable or unacceptable (Attachment M). A fingerstick blood collection procedure is included in the manual (Attachment N). See specimen labeling policy - Attachment L. All staff have been trained on all the above. The technical consultant will monitor for	7/17/13 7/17/13

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E 154	Continued From page 5 testing, how to interpret the results of QC and the corrective action to take if the QC results are unacceptable. 3. The laboratory procedure manual failed to include a step-by-step procedure for using the ALBAcheck - BGS Reagent Control for Anti-D. 4. The laboratory procedure manual failed to include a procedure describing the course of action to take if the Rh(D) testing was unable to be performed (e.g. no Anti-D available, no quality control material available, quality control results unacceptable). 5. The laboratory procedure manual failed to include a step by step procedure for performing fingerstick blood collection including the laboratory's requirements for labeling the specimen, if applicable. B. The ALBAclone Anti-D blend product insert (Z041UQPI/02 June 2010) RECOMMENDED TECHNIQUES states "Slide Technique...Add 1 drop of blood grouping reagent to an appropriately prepared area of a glass slide e.g. a wax pencil oval. Add 1 volume of red blood cells suspended to 30-45% in group homologous plasma/serum. Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at 18-24 degrees C with occasional mixing..." The laboratory procedure titled "Lab Procedures" states "1. Record refrigerator and room temperature in the lab 2. Bring reagents to room temperature (20*-30*)... Rh testing: Mix 1 drop blood and 1 drop of Anti-D Reagent on slide, rock gently (mix) for 30 seconds; incubate (observe) for 5 minutes at Room temp if needed..."	E 154	compliance. There has been no apparent harm to patients, evidenced through QA lookback audit and proficiency testing scores. The laboratory has established a policy for testing Rh typing on each day of testing. Previously tested/documented Rh⊕ and Rh⊖ blood will be used as controls. Records of previously tested control red cells will be kept at clinic in lab and available for review. Reagent and control logs have been combined into one consolidated log to assure complete documentation (Attachment B). All staff have been trained on how to perform and document patient Rh testing, Rh control testing, BGS (ALBAcheck) control requirements for each patient tested, frequency of testing for all tests and what to do if the tests fail for any reason (see all previous Attachments). The	7/17/13 7/17/13

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E 154	Continued From page 6 The laboratory's room temperature range of 20 to 30 degrees C (Celsius) was observed to be outside the manufacturer's specifications of 18-24 degrees C for performing Rh(D) testing using ALBAclone Anti-D. C.1. The ALBAclone Anti-D blend product insert (Z041UQPI/02 June 2010) states "QUALITY CONTROL Quality control of reagents is essential and should be performed with each series of RhD groups, single RhD groups and in accordance with local, state and federal regulations. We suggest that the following red blood cell samples are used to control the reactions of this reagent. Other red blood cell types may be suitable but should be selected with care. O R1r red blood cells should be used as a positive control O rr red blood cells should be used as a negative control" The laboratory procedure titled "Lab Procedures" does not indicate quality control testing using positive and negative Rh(D) red blood cell control material be tested each day patient Rh(D) testing is performed. Review of laboratory testing logs from January 16, 2013 through July 1, 2013, revealed the laboratory performed and reported Rh(D) testing results on 108 patients when no quality control testing was performed (see D5449). 2. The ALBAcheck - BGS Reagent Control for Anti-D product insert (Z271UQPI/01 05 October 2009) states "INTRODUCTION...This reagent is designed to be used as a negative control in	E 154	Technical consultant has trained all testing personnel in all the above (see FY service - E) All facets of the procedure were reviewed with staff, including proper volumes and timing of the procedure. The technical consultant will monitor all systems for compliance. (There has been no apparent harm to patients.) The laboratory now tests a "positive" and "negative" known red-cell control on each day prior to patient testing (See Attachment D). Employees of known and previously tested Rh Type (results on file in Lab) will be used as a ⊕ and ⊖ control with blood being drawn in EDTA properly labeled tubes and used within the 14-day expiration date. Records of control blood are maintained in clinic lab and available for review. A new Rh Typing procedure has been	7/17/13 7/17/13

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E 154	Continued From page 7 conjunction with the following Anti-D products: Z031U, Z036U, Z039U, Z041U...INTENDED PURPOSE ALBAcheck - BGS Reagent Control for Anti-D is intended for use as a negative control in conjunction with Alba Bioscience monoclonal Anti-D reagents...INTERPRETATION OF RESULTS If a positive result is obtained with ALBAcheck - BGS Reagent Control for Anti-D, this will invalidate the test result obtained with the respective ALBA Bioscience monoclonal Anti-D reagent and the red blood cells. The laboratory had no documentation of running the ALBAcheck - BGS Reagent Control for Anti-D with each of the 108 patient Rh(D) tests performed since the facility opened on January 16, 2013.. 3. The ALBAclone Anti-D blend product insert (Z041UQPI/02 June 2010) states "Test Procedures General Information This reagent has been standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed. When a test is required to be incubated for a specific time period, a timer should be used...Slide Technique Add 1 drop of blood grouping reagent to an appropriately prepared area of a glass slide...Add 1 drop of red blood cells suspended to 30-45% in group homologous plasma/serum. Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at 18-24 degrees C with occasional mixing. After incubation, immediately observe macroscopically for agglutination..". While touring the laboratory at approximately 9:10AM., the surveyor observed that there was no timer present on the counter in the testing area. The director stated that they look at the wall clock	E 154	implemented which requires a "+" and "−" control to be run each day of patient testing (Attachment A). All staff have been trained regarding the new Rh Typing procedure, control frequency and testing, and interpretation of all results. An ALBAcheck-BGS reagent control will be run with each patient tested. This is included in the Rh typing overall procedure. Staff have been trained to interpret the BGS results as well (a "negative" control) and know when a test may be invalid. Invalid results addressed in procedure manual, including corrective action if any results fail. A timer has been obtained to ensure proper timing (incubation) for Rh testing. Staff have been inserviced on proper technique of testing, timing of the test, mixing and rocking of slides,	7/17/13 7/17/13

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E 154	Continued From page 8 to see what time the Rh(D) testing was started and continue to check the clock for 5 minutes. He also stated during the interview that only one patient is in the laboratory at a time. During an observation between 11:30AM and 11:40AM., the surveyor observed Rh(D) testing being performed on a patient. Testing personnel (TP) #2 began the Rh(D) testing by placing a drop of ALBAclone Anti-D blend blood grouping reagent on one side of the slide and a drop of the ALBAcheck - BGS Reagent Control for Anti-D on the other side of the glass slide. She then placed a drop of the patient's blood on top of the reagents on each side of the slide, rocked the slide back and forth a few times to mix the red blood cells and the reagents. TP #2 then walked to the other counter in the lab and placed the Hemocue hemoglobin cuvette in the Hemocue analyzer to be tested and asked TP #1 to check on the Rh(D) testing while she brought the patient into another room. The timer was not used to ensure the Rh(D) testing incubated for 5 minutes before the result was determined. In summary, the cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient Rh(D) testing results. Therefore, it is the finding of this agency that the facility neglected to provide the services to assure the health, safety and welfare of the clients.	E 154	use of ⊕ and ⊖ red-cell controls, and use of the ALBAcheck-BGS reagent control. Technical consultant will monitor compliance through competency testing and QA studies to ensure accurate testing. There appears to be no apparent harm done to patients as a result of failure to test "⊕" and "⊖" QC on each day that patients were tested and failure to use the ALBAcheck-BGS reagent control or timer. This is evidenced by results of the QA look back audit and excellent proficiency testing scores, thus reflecting accuracy of testing (Attachment F). Attachment L "documents letter drafted to patients offering re-testing with explanation.	7/17/13
E 155	.0309(D) LABORATORY SERVICES 10A-14E .0309 (d) The facility shall perform and document, at least quarterly, calibration of equipment and validation of test results.	E 155	A new Quality Assessment Plan has been implemented (Attach G). The plan will monitor procedure manual completeness, room temp. records, required performance	7/17/13

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E 155	Continued From page 9 This Rule is not met as evidenced by: Based on review of test records; review of manufacturer's product insert; the absence of documentation on July 2, 2013, procedure review; review of 2013 Rh(D) testing logs; interview with testing personnel (TP); observation; review of 2013 temperature logs, and review of 2013 lab logs, the facility's laboratory staff failed to verify the manufacturer's performance specifications for the ALBAclone Anti-D blend blood grouping reagent before performing patient testing; failed to test a positive and negative red blood cell control at least once each day Rh(D) testing was performed; failed to perform and document corrective action on 15 days between January 16, 2013 through July 1, 2013 when room temperature was outside the manufacturer's specifications for performing Rh(D) testing using ALBAclone Anti-D blend blood grouping reagent; and failed to establish and follow written policies and procedures to monitor, assess, and correct identified problems in the analytic system. Findings include: A. Review of 2013 laboratory patient testing records showed the laboratory began performing Rh(D) testing on patients using ALBAclone Anti-D blend blood grouping reagent on JAnuary 16, 2013. The ALBAclone Anti-D blend product insert (Z041UQPI/02 June 2010) states "SPECIFIC PERFORMANCE CHARACTERISTICS Prior to release, each lot of ALBAclone Anti-D blend is tested by FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity." The facility failed to have documentation available	E 155	Specifications, controls (QC) on days of patient testing, reagent control records, etc. Competency testing is included in the QA plan monitoring to assure proper technique and incubation time for Rh testing. Corrective action for any system failure, testing problem, etc. will be monitored by Technical consultant. Monthly technical consultant visits will monitor staff compliance in all pre-analytical, analytical, and post-analytical processes with a written report submitted to lab director after each visit. All testing personnel have had an inservice on the new QA Plan (See previous Attachments) (see E154)	7/17/13 7/17/13

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THE BAKER CLINIC FOR WOMEN	400-B CRUTCHFIELD ST DURHAM, NC 27704

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E 155	Continued From page 10 to indicate the laboratory had performed and documented testing of known Rh(D) positive and Rh(D) negative individuals to demonstrate they were able to obtain the expected results, positive and negative, when performing testing in their laboratory. During interview at approximately 11:45AM., the laboratory director stated they all tested each other multiple times before they opened the practice and started testing patients. He also stated during the interview that they did not document any of the testing. B. The ALBAclone Anti-D blend product insert (Z041UQPI/02 June 2010) states "QUALITY CONTROL Quality control of reagents is essential and should be performed with each series of RhD groups, single RhD groups and in accordance with local, state and federal regulations. We suggest that the following red blood cell samples are used to control the reactions of this reagent. Other red blood cell types may be suitable but should be selected with care. O R1r red blood cells should be used as a positive control O rr red blood cells should be used as a negative control" The laboratory procedure titled "Lab Procedures" does not indicate quality control testing using positive and negative Rh(D) red blood cell control material be tested each day patient Rh(D) testing is performed. The laboratory "Lab Log" used for documenting Rh(D) testing results includes an area on the top right side of the form for documenting the Rh+	E 155	(See E 154)	7/17/13 7/17/13

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	110748	A. BUILDING: _____ B. WING _____	C 07/02/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE BAKER CLINIC FOR WOMEN	400-B CRUTCHFIELD ST DURHAM, NC 27704

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 155	Continued From page 11 (positive) Control and Rh- (negative) Control lot number, expiration date and result. Review of the "Lab Log" from January 1, 2013 through July 13, 2013, revealed the laboratory documented only the results of an Rh- control result of negative on 1/16/13, 2/20/13, 3/6/13, 4/10/13, 4/15/13, and 5/20/13. On a separate "Lab Log" the laboratory documented positive and negative control results for the ALBAclone Anti- D blend reagent on 6/2/13 and 7/1/13. During interview at approximately 10:50AM, TP #1 stated when she tested the controls on July 1, 2013 she had a positive and negative result. She stated she used a drop from each bottle of ALBAcheck Reagent Control and added a drop of ALBAclone Anti-D and had a positive result on one slide and a negative result on the other slide. Between 10:50AM and 11:10AM, the surveyor observed testing personnel (TP) #1 performing positive and negative quality control testing using the ALBAclone Anti-D blend blood grouping reagent and the ALBAcheck - BGS Reagent Control for Anti-D. TP #1 placed 2 drops of of the ALBAcheck - BGS Reagent Control on 2 glass slides and add 2 drops of ALBAclone Anti-D blend blood grouping reagent to each glass slide. She then rocked the slide to mix the 2 clear reagents together. After approximately 5 minutes there was no visible reaction on either slide. Review of laboratory testing logs from January 16, 2013 through July 1, 2013, revealed the laboratory performed and reported Rh (D) testing results on 108 patients when no quality control testing was performed. C. The ALBAclone Anti-D blend product insert	E 155	(see E154) (see E154)	7/17/13 7/17/13

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	110748	A. BUILDING: _____ B. WING _____	C 07/02/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE BAKER CLINIC FOR WOMEN	400-B CRUTCHFIELD ST DURHAM, NC 27704

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 155	Continued From page 12 (Z041UQPI/02 June 2010) RECOMMENDED TECHNIQUES states "Slide Technique...Add 1 drop of blood grouping reagent to an appropriately prepared area of a glass slide e.g. a wax pencil oval. Add 1 drop of red blood cells suspended to 30-45% in group homologous plasma/serum. Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at 18-24 degrees C with occasional mixing..." Review of temperature logs from January 4, 2013 through July 1, 2013 revealed room temperature in the laboratory was documented as 25 degrees C (Celsius) on 15 of 137 days (1/14/13, 3/2/13, 4/19/13, 4/20/13, 5/2/13, 5/10/13, 5/11/13, 5/17/13, 5/18/13, 6/7/13, 6/8/13, 6/13/13, 6/14/13, 6/15/13, and 6/18/13. Review of the "Lab Log" from January 16, 2013 through July 1, 2013 revealed Rh(D) testing was performed and results reported on 16 patients when room temperature was outside the manufacturer's specifications for testing (3/2/13, 4/19/13, 4/20/13, 5/18/13, 6/7/13, 6/8/13, 6/13/13, 6/14/13, 6/15/13, and 6/18/13). The laboratory failed to have documentation showing they had taken corrective action for any of the 15 days when the temperature was documented as 25 degrees C and patient Rh(D) testing was performed. D. The laboratory failed to have a written quality assessment plan including a description of the laboratory's policy for monitoring, evaluating and correcting problems identified with the Rh(D) testing performed in the laboratory. 1. The procedure manual failed to include	E 155	(See E 154) The laboratory has implemented a temperature log which includes the correct testing temp. to perform Rh testing. The daily testing temp. also recorded on the daily Lab Log along with control and patient testing results. All testing personnel have been inserviced on the importance of making sure the room temp. is within the acceptable testing range (18°-24°C). Staff instructed to adjust thermostat if temp. not in-range for testing, suspend testing until temp. returns to in-range level, and	7/12/13 7/17/13

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	110748	A. BUILDING: _____ B. WING _____	C 07/02/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THE BAKER CLINIC FOR WOMEN	400-B CRUTCHFIELD ST DURHAM, NC 27704

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 155	Continued From page 13 complete instructions for performing Rh(D) testing. . 2. The laboratory's room temperature range was not within manufacturer's requirements for performing Rh(D) testing. 3. The laboratory failed to verify the manufacturer's performance specifications for the Rh(D) testing. 4. The laboratory failed to test positive and negative Rh(D) quality control materials each day of patient testing, failed to include an Rh(D) reagent control with each patient tested, and failed to follow the manufacturer's instructions for incubation of Rh(D) tests. 5. The laboratory failed to perform corrective action when room temperature was outside the manufacturer's specifications for performing Rh(D) testing. In summary, the cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient Rh(D) testing results. Therefore, it is the finding of this agency that the facility neglected to provide the services to assure the health, safety and welfare of the clients.	E 155	document this corrective action on the temp. log. The QA lookback audit included the 16 patients testing on the 15 days the room temp. was out-of-range (25°C). (See previous attachment). There has been no apparent harm to patients as a result of failure to assure proper testing temp. Tech. consultant will monitor for compliance. Excellent proficiency testing scores (100% accuracy) reflect accuracy and reliability of testing. (See E154 for "D. 1.-4.")	7/17/13 7/17/13

Total 108 pts 1/10/13 - 7/1/13

68 days

33

Lab Log

The Baker Clinic For Women

14E, 0309

	Lot #	Exp. Date	Result
Rh+ Control:	[redacted]	[redacted]	[redacted]
Rh- Control:	VII9230	1/10/14	"⊖" 1/16/13

ALBA Check (Quotient) 1/16/13 [redacted]

(18)

Name	DOB	Date	* PTlot#/Exp date	PT	Hgb*	Rh*	Tech
[redacted]	8/30/83	1/16/13	—	—	11.7	⊖	[redacted]
[redacted]	5/1/1971	1/16/13	—	—	12.3	⊕	[redacted]
[redacted]	7.17.93	1.30.13	—	—	12.3	⊕	[redacted]
[redacted]	4-6-88	2-1-13	—	—	12.6	⊕	aeRN
[redacted]	6-5-89	2-1-13	—	—	11.6	⊕	aeRN
[redacted]	8-22-84	2-4-13	—	—	11.9	⊕	aeRN
[redacted]	6.23.90	2.9.13	—	—	14.6	⊕	[redacted]
[redacted]	02-01-91	2-11-13	—	—	12.1	⊕	aeRN
[redacted]	5-31-94	2.12.13	—	—	13.5	⊕	[redacted]
[redacted]	12-5-88	2-15-13	—	—	11	⊕	[redacted]
[redacted]	9-27-84	2-15-13	—	—	9.6	⊕	CK
[redacted]	7-10-80	2-15-13	—	—	13.6	⊕	ae
[redacted]	9.22.91	2.16.13	—	—	10.6	⊕	[redacted]
[redacted]	1-21-89	2.16.13	—	—	11.1	⊕	C Keller
[redacted]	2.23.90	2.16.13	—	—	13.2	⊕	C Keller
[redacted]	1-13-88	2-16-13	—	—	11.1	⊕	C Keller
[redacted]	5-14-92	2-18-13	—	—	15.1	⊕	aeRN
[redacted]	2.13.85	2.2013	04062M5 OK exp. 04/14	⊕	13.6	⊖	[redacted]
						CONTROL VII9230 1/10/14 ⊖ 2/20/13	[redacted]

*HCG dipstick ("1-Step Cassette")
Medical, Supplier 04062M5, 04/14
gb Control: (Lot #/Exp Date)
"Photometer" (Control Cuvette): 12.2 g/dl (±.3) 1/10/14 gb
"Total System" (RDS Systems): _____

* "Anti-D Blend"
"ALBA clone"
(Quotient)
Lot #: VII7718 Exp. Date: 11/2013

Photometer (Control Cuvette): 12.3, ± 0.3 2/20/2013 [redacted]

Lab Log

The Baker Clinic For Women

14E, 0309

(19)

	Lot #	Exp. Date	Result
Rh+ Control:			
Rh- Control:	V119230	1-10-14	"−" 3/6/13

ALBA Check (Quotient)

Name	DOB	Date	* PTlot#/Exp date	PT	Hgb*	Rh*	Tech
[redacted]	9-20-93	2/22/13	—	—	13.2	+	aeRN
[redacted]	5-14-92	2.23.13	—	—	11.3 g/dl	N/A	EYRN
[redacted]	11-12-81	2-27-13	—	—	13.5 g/dl	N/A	EYRN
[redacted]	7-14-94	3-1-13	—	—	13.2	+	aeRN
[redacted]	7-31-81	3-1-13	—	—	10.9	+	aeRN
[redacted]	8-11-92	3-2-13	—	—	13.0 g/dl	+	EYRN
[redacted]	7-31-95	3-4-13	—	—	13.4	+	EYRN
[redacted]	11-2-89	3-6-13	—	—	13.6	+	aeRN
[redacted]	3-2-92	3-8-13	—	—	12.2	+	aeRN
[redacted]	1-13-94	3-15-13	—	—	11.3	+	aeRN
[redacted]	3-14-93	3-16-13	—	—	11.8	+	EYRN
[redacted]	4-5-92	3-25-13	—	—	13.9	+	CK
[redacted]	01-09-95	3-25-13	—	—	12.1	+	CK
[redacted]	11-14-92	3-29-13	—	—	13.3	+	CK
[redacted]	9-15-80	4-3-2013	—		12	+	CK
[redacted]	12-3-87	4-3-2013	—	—	11.6	+	CK
[redacted]	7-11-88	4-5-2013	—	—	11.5	+	CK
[redacted]	3 29.91	4-6-2013	—	—	13.6	+	CK
[redacted]	1-18.88	4-10-2013	—	—	11.1	+	CK
						Control V119230	

6-10-14 "−" 4/10/13

*HCG dipstick ("1-Step Cassette")
Medical, Supplier

*Hgb Control: (Lot #/Exp Date)
"Photometer" (Control Cuvette): 12.3 ± 0.3 4/6/13
"Total System" (RDS Systems):

* "Anti-D Blend"
"ALBA clone"
(Quotient)
Lot #: V117718 Exp. Date: 11/23/13

Lab Log

The Baker Clinic For Women

14E, 0309

Date: 4/15/2013 - 5/18/2013

	Lot #	Exp. Date	Result
Rh+ Control:			
Rh- Control:	V119230	1-10-14	"⊖" 4/15/13 JHB

ALBA Check (Quotient)

(20)

Name	DOB	Date	* PTlot#/Exp date	PT	Hgb*	Rh*	Tech
[redacted]	4-10-86	4-15-2013			12.6	⊕	C Kell
[redacted]	8-6-99	4-19-2013			8.0	⊕	N Lee RN
[redacted]	9-24-84	4-20-2013			11.3	⊕	C Kell
[redacted]	9-16	4-20-2013			11	⊕	C Kell
[redacted]	2-5-85	4-22-13			12.8	⊕	C Kell
[redacted]	10-1-91	4-22-13			11.1	⊕	C. Kell
[redacted]	1-22-85	4-24-13			11.2	⊖	C Kell
[redacted]	1/2/1970	4-26-13		⊖			C Kell
[redacted]	8-12-83	4-27-13			13.7	⊕	C Kell
[redacted]	4-27-79	5-4-13			11.9	⊕	C Kell
[redacted]	1/14/1981	5-4-13			15.5	⊕	C Kell
[redacted]	10/29/86	5-6-13			12.5	⊕	C Kell
[redacted]	1/5/93	5-8-13			11	⊕	C Kell
[redacted]	8/23/77	5-8-13			11.1	⊖	C Kell
[redacted]	10/9/91	5-8-13			11.7	⊕	JRobert
[redacted]	5/8/85	5-9-13			12.2	⊕	C Kell
[redacted]	12/10/94	5-13-13			8.6	⊕	C Kel
[redacted]	7/2/73	5-14-13			11.6	⊕	C Kell
[redacted]	2-1-93	5-15-13			10.0	⊕	C Kell
[redacted]	9-20-94	5-18-13			14.2	⊕	C Kel

*HCG dipstick ("1-Step Cassette")
Medical, Supplier 04062m 5/4-14

*Hgb Control: (Lot #/Exp Date)
"Photometer" (Control Cuvette): 12.3 ± 0.3 5/18/13 JHB
"Total System" (RDS Systems): _____

* "Anti-D Blend" see control log
"ALBA clone"
(Quotient)
Lot #: V119718 Exp. Date: 11/23/13

Lab Log

The Baker Clinic For Women

14E, 0309

Date: 5/20/2013 - 6/6/2013

	Lot #	Exp. Date	Result
Rh+ Control:			
Rh- Control:	V11 9230	1/10/14	⊖ 5/24/13 ji

(20)

ALBA Check (Quotient)

Name	DOB	Date	* PTlot#/Exp date	PT	Hgb *	Rh*	Tech
[redacted]	5/16/85	5-20-2013			9.8	+	C. Keller
[redacted]	12/a/86	5-20-13			13.3	+	C Keller
[redacted]	11/12/85	5-20-13			13.1	+	C. Keller
[redacted]	1-11-81	5.24.13			12.7	+	C Kell
[redacted]	12.8-90	5.24-13			10.2	+	C Kell
[redacted]	11-18.90	5-25-13			11.5	−	C Kell
[redacted]	7-16.87	5-28-13			10	+	C Kell
[redacted]	10-5.87	5/31/13			11.2	+	C Kell
[redacted]	7-8-87	5/31/13			13.4	+	Robert
[redacted]	11-16-95	6-1-13			11.2	+	C Kell
[redacted]	12-25-85	6-1-13			11.1	+	C Kell
[redacted]	3-21-84	6-1-13			11.7	+	Robert
[redacted]	1-8-88	6-4-13			14.1	+	C Kell
[redacted]	2-8-81	6-4-13			12.4	+	C Kell
[redacted]	5-24-96	6.6.13			10.2	+	C Kell
[redacted]	7-18.93	6-6-13			11.2	+	C Kell
[redacted]	2-8-87	6-6-13			10.7	+	C Kell
[redacted]	10.28.84	6-6-13			11.4	+	C Kell
[redacted]	4-12-81	6-6-13			9.5	+	C Kell
[redacted]	10.21-88	6.6-13			12.4	+	C Kell

*HCG dipstick ("1-Step Cassette")
. Medical, Supplier 5.6 11.2 15.6
*gb Control: (Lot #/Exp Date) 5/28/13 GH1123 CK
"Photometer" (Control Cuvette): 12.3 (+/- 0.3) 5/18/13 ji
"Total System" (RDS Systems): 5.6 11.2 15.6 Results
5/29/13 C Keller

* "Anti-D Blend" See control log
"ALBA clone"
(Quotient)
Lot #: V117718 Exp. Date: 11/2013

Lab Log

The Baker Clinic For Women

HE, 0309

Date: 6/7/2013 - 6-25-13 (20)

	Lot #	Exp. Date	Result
Rh+ Control:			
Rh- Control:			

Name	DOB	Date	* PTlot#/Exp date	PT	Hgb*	ALBA Check (Quotient) Rh*	Tech
[redacted]	6/30/79	6-7-2013			13.6	+	C Kelle
[redacted]	1-26-94	6-8-2013			11.1	+	C Kelle
[redacted]	3-3-73	6-8-2013			12.3	−	C Kelle
[redacted]	1-8-87	6-10-2013			10.1	+	C Keller
[redacted]	9-11-87	6-11-2013			11.8	+	C Kelle
[redacted]	12-17-92	6-13-2013			13.4	+	C Kelle
[redacted]	6-12-76	6-13-2013			10.1	+	C Kelle
[redacted]		6-15-2013			8.2	+	C Kelle
[redacted]	9-6-85	6-15-2013			14.1	+	C Kelle
[redacted]	7-18-82	6-15-2013			12.9	+	C Kelle
[redacted]	8-1-84	6-15-2013			10.8	+	C Kelle
[redacted]	12-26-94	6-15-2013			13.7	+	C Kelle
[redacted]	8-21-84	6-18-2013			11.6	+	C Kelle
[redacted]	10-24-89	6-20-13			12.2	−	C Kelle
[redacted]	1-18-77	6-20-13			15.0	−	C Kelle
[redacted]	8-4-94	6-22-13			10.8	+	C Kelle
[redacted]	8-3-93	6-24-13			12.3	−	C Keller
[redacted]	9-20-87	6-24-13			12.9	+	C Kelle
[redacted]	6-6-93	6-25-13			10.7	+	C Kelle
[redacted]	4-4-85	6-25-13			11.2	+	J Roberts

*HCG dipstick ("1-Step Cassette")
. Medical, Supplier
*gb Control: (Lot #/Exp Date)
"Photometer" (Control Cuvette):_____
"Total System" (RDS Systems):_____

* "Anti-D Blend"
"ALBA clone"
(Quotient)
Lot #: _____ Exp. Date:_____

Lab Log

The Baker Clinic For Women

(11)

HE, 0309

Date: 6/25/13

	Lot #	Exp. Date	Result
Rh+ Control:			
Rh- Control:			

Name	DOB	Date	* PTlot#/Exp date	ALBA Check (Quotient) PT	Hgb *	Rh*	Tech
[redacted]	5/20/95	6/26/13		+	11.9	+	robert
[redacted]	2/24/78	6/27/13		+	13.5	+	C Kelly
					~~13.5~~	+	~~C Kelly~~
[redacted]	6-3-92	6/27/13			10.8	+	C Kelly
[redacted]	1-24-74	6/27/13			12.4	+	C Kelly
[redacted]	11-22-59	6/28/13			12.4	+	C Kelly
[redacted]	9-29-86	6/28/13			10.8	+	C Kelly
[redacted]	3-12-80	6/28/13			12	+	C Kelly
[redacted]	12/5/1987	6/26/13			~~12.3~~ 13	+	robert
[redacted]	1/9/52	6/29/13		+			C Kelly
[redacted]	5/3/85	6/29/13			11.4	+	C Kelly
[redacted]	9-16-86	7-1-2013			10.6	+	C Kelly

*HCG dipstick ("1-Step Cassette")
. Medical, Supplier

* Hgb Control: (Lot #/Exp Date)
"Photometer" (Control Cuvette): 12.3 (± 0.3) 6/25/13 jer
"Total System" (RDS Systems): _____

* "Anti-D Blend" see control log
"ALBA clone"
(Quotient)
Lot #: V117718 Exp. Date: 11/23/13

Lab Log

The Baker Clinic For Women

14E, 0309

Date: _____

	Lot #	Exp. Date	Result
Rh+ Control:			
Rh- Control:			

Name	DOB	Date	* PTlot#/Exp date	PT	Hgb *	Rh*	Tech
Anti D Blend		6/2/13	Lot V119230 2014-1-10			(-)	C Keller
Anti D Blend		6/2/13	Lot V119230 2014-1-10			(+)	C Keller
Anti D Blend		7/1/13	Lot V119230 2014-1-10			(+)	C Keller
Anti D Blend		7/1/13	Lot V119230 2014-1-10			(-)	C Keller
Hemoglobin		7/1/13	Lot Gh112		5.4 12.6 15.2		C Keller
Hemoglobin		7/1/13	Control Cuvet		12.3		C. Keller

ALBAcheck B65 Reagent control for Anti-D

*HCG dipstick ("1-Step Cassette")
.. Medical, Supplier

* Hgb Control: (Lot #/Exp Date)
"Photometer" (Control Cuvette): (2.3 ± 0.3 g/dl (7/1/13)
"Total System" (RDS Systems): _____

* "Anti-D Blend"
"ALBA clone"
(Quotient)
Lot #: _____ Exp. Date: _____