Curtis Boyd M.D., P.C.
522 Lomas Boulevard NE
Albuquerque, New Mexico 87102

December 12th, 2017

To Whom It May Concern,

Based on the report from the 12/6/17 CLIA site survey performed at our clinic, a box containing expired Alere hCG pregnancy testing cassettes was discovered to be in use. All expired cassettes were disposed of immediately that same day. Twelve of those cassettes were used in patient care. All twelve patients were accounted for. Of the twelve, five were "positive" and seven were "negative." Among the "positive" tests:

- Two patients received abortion services. Their pregnancies were confirmed using ultrasound.
- One patient was referred to the UNM Center for Reproductive Health to rule out the possibility of an ectopic pregnancy. Services included a repeat pregnancy test and subsequent treatment for an ectopic pregnancy.

The remaining nine patients were a mix of "positive" and "negative" results. These were "walk-in" patients who only received pregnancy testing at our clinic. At that time it had been the clinic policy to obtain the patient's name and date of birth for this service. For that reason, any attempts to notify them were not possible.

Several changes were made to correct this:

- The lab log was updated on 12/12/18 to include a space for entering lot numbers and expiration dates for pregnancy testing cassettes. This is performed daily whenever pregnancy testing is offered. It is entered by any testing personnel. The Lab Supervisor performs a daily review of the lab log, ensuring this information has been recorded in the log. The Lab Supervisor writes down his initials and the date performed at the bottom of the log.
- Pregnancy testing documentation has been updated to include a space for entering a patient's contact information, including their phone number and address. If there ever is a subsequent problem with pregnancy testing cassettes, this record can now be used to notify them.

Daniel Hicks, RN is responsible for these corrections. Copies of both the Lab Log and Request for Pregnancy Testing forms have been included with this letter for your review.

Thank you for your help with this matter.

Steve Thompson
Nursing and Lab Supervisor

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 02/09/2018
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	32D0534781	A. BUILDING _____ B. WING _____	12/06/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CURTIS BOYD MD PC	522 LOMAS BLVD NE ALBUQUERQUE, NM 87102

(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) COMPLETION DATE
D 000	INITIAL COMMENTS The following deficiencies were cited during a recertification survey completed on December 6, 2017 for the federal laboratory requirements of 42 CFR Part 493 .	D 000		
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer instructions, patient test logs and interviews with laboratory staff, the laboratory failed to follow manufacturer instructions and discard expired pregnancy test kits when expired. This failed practice could result in the use of test kits that are not functioning correctly. Findings are: 1. Observation of laboratory supplies and review of manufacturer labeling on 12/06/17 at 11:58 am revealed the laboratory had not discarded expired pregnancy test kits and used them for patient testing. a. Alere hCG (for urine pregnancy) lot HCG5060045 expiration date 04/2017 28 of 40 cassettes were remaining in the box. There was no documentation of the open date or the received date on the box. b. Alere hCG lot HCG5100027 expiration date	D1001	All expired tests were immediately disposed of. The lab log was updated on 12/12/17 by the RN to include a daily recording of lot numbers and expiration dates of pregnancy test cassettes and hemoglobin microcuvettes. The Lab Supervisor will review the log daily and initial and date the log upon review. (Please see attached letter for additional information regarding expired pregnancy tests)	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: [signature] TITLE: MD/laboratory director (X6) DATE: 2/28/2018

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer instructions, patient test logs and interviews with laboratory staff, the laboratory failed to follow manufacturer instructions and discard expired pregnancy test kits when expired. This failed practice could result in the use of test kits that are not functioning correctly. Findings are: 1. Observation of laboratory supplies and review of manufacturer labeling on 12/06/17 at 11:58 am revealed the laboratory had not discarded expired pregnancy test kits and used them for patient testing. a. Alere hCG (for urine pregnancy) lot HCG5060045 expiration date 04/2017 28 of 40 cassettes were remaining in the box. There was no documentation of the open date or the received date on the box. b. Alere hCG lot HCG5100027 expiration date	D1001	All expired tests were immediately disposed of. The lab log was updated on 12/12/18 by the RN to include a daily recording of lot numbers and expiration dates of pregnancy test cassettes and hemoglobin microcuvettes. The Lab Supervisor will review the log daily and initial and date the log upon review. (Please see attached letter for additional information regarding expired pregnancy tests)	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D1001	Continued From page 1 08/2017 This box was unopened with no indication of when it was received into the laboratory. c. Alere hCG lot HCG5120221 expiration date 11/2017. This box was unopened with no indication of when it was received into the laboratory. 2. During interview on 12/06/17 at 12:00 pm TP #5 stated that the open date of the test kits were not documented. TP #5 further stated at 12:53 pm that he (the laboratory) had been unable to find the shipping records for the kits. 3. The laboratory director did not comment on this finding during the exit interview on 12/06/17 at 1:00 pm.	D1001		
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the review of 2016-2017 proficiency testing records, laboratory policies, the CMS Form 209 Personnel Report Form, personnel records, and interviews with laboratory staff, the laboratory failed to ensure that all testing personnel participated in proficiency testing. This failed practice could result in the laboratory not having any personnel trained on proficiency testing and failing to report results prior to the due date.	D2007		

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D2007	Continued From page 2 Findings are. 1. Review of 2016-2017 proficiency testing records revealed only 2 of the laboratory's current testing personnel had participated in proficiency testing over the 2 year period. TP #5 was identified as the testing person for 3 of 5 test events, 2nd event 2016, 3rd event 2016, and 1st event 2017. TP #3 was identified as the testing person for the 2nd event of 2017. 2. Review of the CMS Form 209 Personnel Report Form, completed by the laboratory, indicated the laboratory currently had 5 testing personnel. 3. Review of personnel files revealed that 5 of 5 testing personnel, TP #1-#5 had been employed and trained to perform Rh testing prior to 2016. 4. Review of laboratory policies did not reveal any written policies concerning the testing proficiency samples. 5. Testing person #5, the laboratory supervisor, confirmed this finding during interview on 12/06/17. The laboratory director did not comment on this finding during the exit conference on 12/06/17 at 1:00 pm.	D2007	On 2/13/18 the Lab Director instituted a rotating schedule for testing personnel to perform proficency testing. The hard copies of this testing will be kept in the CLIA manual in chronological order and will serve as a schedule for this rotation. Testing personnel who have not yet done proficiency testing will be the first on this schedule. Each TP will then complete the testing as the test packets arrive until all have completed it. The next API testing samples will arrive at the clinic in April of 2018.	
D5413 510M	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the	D5413		

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D5413	Continued From page 3 manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, the review of patient test records, laboratory policy, temperature records, and interviews with laboratory staff, the laboratory failed to monitor the refrigerator temperature each day the clinic was open. This failed practice could result in the laboratory's delayed identification of equipment failure and the loss of reagents and other supplies stored in the refrigerator. Findings are: 1. Review of January - June 2016 and January - September 2017 refrigerator temperature records revealed a trend of documenting the temperature only 4 days per week. 2. Review of the laboratory policy indicated that the laboratory used whole blood samples from staff as control materials for Rh testing. 3. Observation of the refrigerator contents on 12/06/17 at 12:00 pm confirmed that the control samples and reagents were stored in the refrigerator. 4. During interview on 12/06/17 at 12:00 pm, the	D5413	On 2/13/18 the Lab Director designated testing personnel responsible for recording refrigerator temperatures daily whenever the clinic is open. The Lab Supervisor now monitors the temperature log on a weekly basis to ensure this is performed, and initials the log.	

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D5413	Continued From page 4 supervisor, (Testing Person #5) stated that the laboratory did not perform Rh testing on Mondays because nursing staff were not in the office. He also stated that the clinic was open to walk-in patients and urine pregnancy tests might be performed. 5. The laboratory director did not comment on this finding during the exit interview on 12/06/17 at 1:00 pm.	D5413		
D5449 510M	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of patient test records, quality control records, laboratory policies and interview with the laboratory director, the laboratory failed to perform and document a positive and negative control each day of patient testing. This failed practice could likely result in the reporting of erroneous patient results. The laboratory performed 11 Rh tests on 6/20/16 and 7 on 7/7/17. Findings are:	D5449		

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D5449	Continued From page 5 1. Review of January - June 2016 and January - September 2017 patient testing/quality control logs revealed 2 test days when the laboratory failed to perform a positive and negative control. a. For 1 of 16 test days in June 2016, the laboratory failed to perform and document the positive and negative control for Rh testing. 11 patients were tested (P#1-11). b. a. For 1 of 16 test days in July 2017, the laboratory failed to perform and document the positive and negative control for Rh testing. 7 patients were tested (P#12-19). 2. Review of the laboratory quality assurance policy indicated that the nursing supervisor was responsible for oversight of quality control. There was no documentation in the patient/quality control log that indicated review by the supervisor (Testing Person #5). 3. The laboratory director did not comment on these findings during the exit interview on 12/06/17 at 1:00 pm.	D5449	On 2/13/18 the RN ammended the lab log to include a space for the Lab Supervisor to enter his initials. A review of the lab log is now performed by the Lab Supvisor on a daily basis. This review is performed to ensure all patient information has been entered, daily controls have been performed, and perishable testing items do not exceed their expiration dates.	
D5793 510M	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.	D5793		

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D5793	Continued From page 6 This STANDARD is not met as evidenced by: Based on the review of patient test records, temperature records, quality control records, laboratory policies and interview with laboratory staff, This failed practice could likely result in failure to identify failures in the laboratory and perform corrective actions. Findings are: 1. The laboratory failed to perform and document a positive and negative control each day of patient testing. See D5449 2. The laboratory failed to monitor and document the laboratory refrigerator temperature each day of the laboratory was open. See D5413 3. Review of laboratory policies indicated that quality assurance activities would be part of the monthly meetings. However, there was no documentation in any of the 2016-2017 meetings that addressed the failure to perform quality control or the failure to document refrigerator temperatures. 4. The laboratory director did not comment on these findings during the exit interview on 12/06/17 at 1:00 pm.	D5793	On 2/13/18 the Clinic Manager and Lab Director implemented a tri-annual lab quality assurance review meeting. During this meeting, a review of quality control topics, including adherence to quality control policies and accountability, will be discussed with relevant staff members and the Lab Supervisor. The persons attending will sign an attendence form showing their participation in the QA review. The first meeting will be 4/9/18, and will be repeated in August and December. On 2/15/18 a Tri-Annual review was created by the RN. This will be performed in April, August, and December of every year. Six charts and their corresponding lab entries will be inspected for accuracy and adherenceto lab policies. The results will then be signed off by the Lab Supervisor and Lab Director. The first will be 4/9/18. This form has been attached to this review.	
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for	D6004	On 2/15/18 an annual review was created by the RN to begin in 12/18 and every subsequent December with the entire lab testing team. Data will be compiled from the previous years tri-annual reviews and discussed. Action plans will be created for the upcoming year to address any deficiencies. The Lab Director will be responsible for conducting the meeting. The Lab Supervisor will be responsible for overseeing any changes resulting from the annual meeting.	

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D6004	Continued From page 7 assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, proficiency test records, personnel records, and interview with laboratory staff, the laboratory director failed to provide overall direction of the laboratory. Findings are: 1. The laboratory failed to perform and document a positive and negative control each day of patient testing. Review of January - June 2016 and January - September 2017 patient testing/quality control logs revealed 2 test days when the laboratory failed to perform a positive and negative control. a. For 1 of 16 test days in June 2016, the laboratory failed to perform and document the positive and negative control for Rh testing. 11 patients were tested (P#1-11). b. a. For 1 of 16 test days in July 2017, the laboratory failed to perform and document the positive and negative control for Rh testing. 7 patients were tested (P#12-19). See D5449	D6004	On 2/13/18 the Clinic Manager and Lab Director implemented a tri-annual lab quality assurance review meeting. During this meeting, a review of quality control topics, including adherence to quality control policies and accountability, will be discussed with relevant staff members and the Lab Supervisor. The persons attending will sign an attendence form showing their participation in the QA review. The first meeting will be 4/9/18, and will be repeated in August and December. On 2/15/18 a Tri-Annual review was created by the RN. This will be performed in April, August, and December of every year. Six charts and their corresponding lab entries will be inspected for accuracy and adherenceto lab policies. The results will then be signed off by the Lab Supervisor and Lab Director. The first will be 4/9/18. This form has been attached to this review. On 2/15/18 an annual review was created by the RN to begin in 12/18 and every subsequent December with the entire lab testing team. Data will be compiled from the previous years triannual reviews and discussed. Action plans will be created for the upcoming year to address any deficiencies. The Lab Director will be responsible for conducting the meeting. The Lab Supervisor will be responsible foroverseeing any changes resulting from the annual meeting.	

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D6004	Continued From page 8 2. The laboratory failed to monitor and document the laboratory refrigerator temperature each day of testing. See D5413 3. Review of laboratory policies indicated that quality assurance activities would be part of the monthly meetings. However, there was no documentation in any of the 2016-2017 meetings that addressed the failure to perform quality control or the failure to document refrigerator temperatures. 4. The laboratory director did not comment on these findings during the exit interview on 12/06/17 at 1:00 pm.	D6004		
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the review of 2016-2017 proficiency testing records, laboratory policies, the CMS Form 209 Personnel Report Form, personnel records, and interviews with laboratory staff, the laboratory director failed to ensure that all testing	D6016		

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D6016	Continued From page 9 personnel participated in proficiency testing. Findings are: 1. Review of 2016-2017 proficiency testing records revealed only 2 of the laboratory's current testing personnel had participated in proficiency testing over the 2 year period. TP #5 was identified as the testing person for 3 of 5 test events, 2nd event 2016, 3rd event 2016, and 1st event 2017. TP #3 was identified as the testing person for the 2nd event of 2017. 2. Review of the CMS Form 209 Personnel Report Form, completed by the laboratory, indicated the laboratory currently had 5 testing personnel. 3. Review of personnel files revealed that 5 of 5 testing personnel, TP #1 - TP #5 had been employed and trained to perform Rh testing prior to 2016. 4. Review of laboratory policies did not reveal any written policies concerning the testing proficiency samples. 5. Testing person #5, the laboratory supervisor, confirmed this finding during interview on 12/06/17. The laboratory director did not comment on this finding during the exit conference on 12/06/17 at 1:00 pm.	D6016	On 2/13/18 the Lab Director instituted a rotating schedule for testing personnel to perform proficency testing. The hard copies of this testing will be kept in the CLIA manual in chronological order and will serve as a schedule for this rotation. Testing personnel who have not yet done proficiency testing will be the first on this schedule. Each TP will then complete the testing as the test packets arrive until all have completed it. The next API testing samples will arrive at the clinic in April of 2018. On 2/13/18 the Lab Director implemented an annual skills evaluation for all testing personnel. This includes a written exam and a performance exam. The Lab Supervisor will oversee all skills evaluation, and the Lab Director will sign off on the TP's certification. This will first be performed at the annual Lab QA meeting in December. Copies of these forms have been included for review.	
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of	D6030		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	32D0534781	A. BUILDING _____ B. WING _____	12/06/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CURTIS BOYD MD PC	522 LOMAS BLVD NE ALBUQUERQUE, NM 87102

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D6030	Continued From page 10 personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must– (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the review of proficiency testing records, personnel records, laboratory and interview with the laboratory director, the laboratory director failed to ensure that policies were established for monitoring the competency of testing personnel. This failed practice could likely result in failure to identify training needs of testing personnel. Findings are: 1. Review of personnel records revealed the laboratory director/technical consultant had not conducted new competency evaluations for 5 of 5 testing personnel (TP #1- TP #5) hired prior to the last survey on 12/14/2015. a. The competency documents had been completed and signed by the previous laboratory director and consisted of a checklist and no supporting documentation of how the evaluations	D6030	On 2/13/18 the Lab Director and Lab supervisor agreed to include competency review as part of the testing staff's tri-annual meeting. A staff member designated by the Lab Supervisor will demonstrate to the testing personnel rh and hgb testing technique on stored blood. The TP's perfomance will afterward be discussed with the lab testing team. The person performing the testing will rotate based on the Lab Supervisor's designation. The next scheduled competency evaluation will be held on 4/9/18.	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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D6030	Continued From page 11 were performed. b. The only indication of current competency evaluations was under the section "Review Dates" but the individual checklist items were not initialed by the current laboratory director for the 2016-2017 evaluations. 2. Review of proficiency test records revealed that only 2 (TP #3 and TP #5) of the current 5 testing personnel had participated in proficiency testing since 2015 so proficiency testing could have not been used as part of the evaluation of testing personnel competency. 3. Review of the laboratory's policies revealed that there was no defined policy on how to evaluate the competency of testing personnel. 4. The laboratory director did not comment on this finding during the exit conference on 12/06/17 at 1:00 pm.	D6030		