

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1014173	(X3) Date Survey Completed 11/07/2019
Name of Provider or Supplier A Preferred Women's Health Center	Street Address, City, State 3220 Latrobe Dr, Charlotte, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's product instructions, review of laboratory procedures and laboratory logs, observation, and testing personnel (TP) interview 11/7/19, the laboratory failed to follow manufacturer's instructions and the laboratory's procedure for the HemoCue Hemoglobin (Hb) 201 microcuvettes used with the HemoCue Hb 201+ analyzer. Findings: 1. The HemoCue Hb 201 Microcuvettes product insert states "... Storage and Handling Use HemoCue Hb 201 Microcuvettes prior to expiry date on each package. ... Once the seal of the vial is broken the microcuvettes in the vial are stable for three months. ..." Review of laboratory logs revealed Hb microcuvettes were documented as expired and were used for patient testing on the following dates: a. 10/5/17, 10/6/17, 10/7/17 - lot #1703078, expired 1/5/17; b. 10/28/17 - lot #1706257, expired 1/28/17; c. 10/30/17,10/31/17 - lot #1708320, expired 1/28/17; d. 11/1/17 - lot #1708320, expired 1/30/17; e. 11/24/17, 11/25/17 - lot #1706237, expired 2/22/17; f. 11/28/17,11/29/17, 12/1/17 - lot #1706237, expired 2/27/17; g. 12/7/17, 12/8/17, 12/9/17 - lot #1706237, expired 3/6/17. During interview at approximately 11am, TP#1 confirmed the Hb microcuvettes were documented as being expired. She stated the TP had trouble documenting the correct 3-month expiration date for the microcuvette vials once opened. 2. The HemoCue 201 Microcuvettes product insert states "... Store at room temperature (15-30 degrees C (Celsius), 59-86 degrees F (Fahrenheit) in a dry place. ... Note: Always keep the vial properly closed. ... Limitations a) Fill the microcuvette within 3 minutes after removal from the package. ... Procedure ... Note: The microcuvette should be filled within 3 minutes after the microcuvette has been taken out of its package. ... " The laboratory's</p>

HemoCue Hb 201+ procedure states under "Reagents and Storage...Once opened, the microcuvettes are stable for 3 months..." The procedure also states, "...2. Remove a cuvette from the vial with a dry hand and replace the cap tightly to avoid humidity damage to the remaining cuvettes." During tour of laboratory at approximately 12pm, the surveyor observed an open vial of microcuvettes on the laboratory counter. The contents of the vial were emptied into a cardboard box lid on the counter. During interview at approximately 12:15pm, TP #3 confirmed she empties the microcuvettes into the cardboard box lid first thing in the morning and places them back in the vial at the end of the day. She stated she was unaware the microcuvettes needed to be kept in a closed vial until time of patient testing. 3. The laboratory's "Critical Values List" states "The following are the alert values specific for (the laboratory). Repeat any specimen with results occurring within the parameter listed below. ..." A notation dated 11/7/19 stated that Hemoglobin values less than 10.0 g/dl (grams per deciliter) are considered critical/alert values. Random review of 2019 daily logs revealed repeat testing of hemoglobin values below 10.0 was not routinely documented. Examples: a. On 6/29/19, patient #40 had a hemoglobin of 8.0 g/dl with no documentation of repeat testing; b. On 8/2/19, patient #12 had a hemoglobin of 6.6 g/dl with no documentation of repeat testing; c. On 8/5/19, patient #29 had a hemoglobin of 7.4 g/dl with no documentation of repeat testing; d. On 9/17/19, patient #7 had a hemoglobin of 8.7 g /dl with no documentation of repeat testing. During interview at approximately 11:30 a.m., TP # 1 stated that they usually repeat hemoglobins below 10. She stated that if the two readings are comparable, the repeat test is not always documented.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on review of 2017, 2018, and 2019 Quality Control (QC) records, absence of documentation, and interview with the Technical Consultant(TC) 11/7/19, the laboratory failed to retain all required records for at least 2 years. Findings: The laboratory performs Rhesus D (RhD) antigen testing using Anti-D Blend ALBAclone Blood Grouping Reagent. QC is performed each day of patient testing using Quotient ALBAcyte Reagent red blood cells - cell #1 as a positive control and cell #3 as a negative control. Review of QC records revealed the laboratory failed to retain the ALBAcyte Red blood cell assay sheets with appropriate antigen typing for the control lot numbers in use in 2017, 2018, and 2019. During interview at approximately 11:30am., the TC confirmed the laboratory did not retain the assay sheets.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on the review of manufacturer's instructions, review of laboratory procedure, observation, and technical consultant(TC) interview 11/7/19, the laboratory failed to follow manufacturer's instructions for Rhesus D antigen (RhD) testing. Review of manufacturer's instructions for RhD testing, ALBAclone Anti-D blend blood grouping reagent, revealed under "Slide technique... 1. Add 1 drop of blood grouping reagent... 2. Add 1 drop of whole blood...3. Mix well by rocking the slide for approximately 30 seconds and incubate the test at 20-24 degrees Celsius(C) for 5 minutes with occasional mixing. 4. After incubation, immediately observe macroscopically for agglutination." The laboratory performs a BGS control with each patient tested. The manufacturer's instructions for ALBAcheck-BGS Reagent Control for Anti-D states the BGS reagent control "should be substituted for, and used by the recommended techniques for the monoclonal Anti-D reagent being controlled." The laboratory's procedure "Anti D blend ALBAclone Blood Grouping Reagent" states "...Mix well by rocking the slide for approximately 30 seconds and incubate the test for 5 minutes at 18-24C with occasional mixing....After incubation, immediately observe macroscopically for agglutination..." The procedure fails to follow the manufacturer's instruction for incubation temperature...the manufacturer states to incubate at 20-24 degrees C, not 18-24 degrees C. During tour of the laboratory at approximately 12:15pm., the surveyor observed TP#3 rock the slide for approximately 30 seconds and immediately interpret the test. The TP failed to incubate the slide for 5 minutes as stated in the manufacturer's instructions and the laboratory's procedure. Interview with the TC at approximately 12:30pm. confirmed patient test results that come up positive after rocking for 30 seconds are interpreted and are not incubated for the full 5 minute time-frame.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, review of the laboratory's 2018 and 2019 quality assessment records, review of 2019 daily logs, and interview with the TC (technical consultant) 11/7/19, the laboratory failed to evaluate all patients tested on 2 days when expired quality control material was used for patient testing. Findings: The manufacturer's product insert for the Quotient ALBAcyte Antibody Screening Cells states "... PRECAUTIONS ... Do not use beyond the notified expiry date. ..." Review of the laboratory's 2018 and 2019 quality assessment records revealed it was discovered during the TC visit 4/1/19 that the quality control material (lot #V203130) used by the laboratory on 1/22/19 and 1/23/19 had expired 1/21/19. Review of 2019 patient logs revealed that 17 patients were tested 1/22/19 and 13 patients were tested 1/23/19. During interview at approximately 9:30 a.m., the TC stated that the laboratory did not receive their order of quality control material on time, so the only control material they had was the expired lot number V203130. She stated they were told by

clinic management it was OK to use the expired controls and continue patient testing. She stated she performed a "random" audit of 10 patients and determined that patient testing was not affected. She confirmed all 30 patient records were not reviewed.