

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0469836	(X3) Date Survey Completed 11/02/2020
Name of Provider or Supplier Goddard Health Center / Ou Health Services	Street Address, City, State 620 Elm Ave, Norman, OK	
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
D0000	The recertification survey was performed on 11/02/2020. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director and laboratory manager during an exit conference performed at the conclusion of the survey.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a written general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On 11/02/2020 at 11:00 am, the laboratory manager stated to the surveyor high complexity manual differentials, which included identification of cells more immature than a band, were performed in the laboratory; (2) The surveyor reviewed personnel records for competency assessments performed during 2018 and to date in 2020. There was no evidence competencies had been performed for the general supervisor based on their job responsibilities; (2) The surveyor asked the laboratory manager if a written policy to evaluate the general supervisor, based on job responsibilities, was available and if competencies had been performed during the review period. The laboratory manager stated to the surveyor on 11/02/2020 at 11:30 am, a policy to evaluate the general supervisor based on job responsibilities had not been written; and competencies had not been performed.</p>
D5413	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 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 a review of records, manufacturer's instructions, and interview with the laboratory director and laboratory manager, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) On 11/02/2020 at 11:00 am, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XNL-430 analyzer; (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer in the operator's manual. Chapter 5, Section 5.1 "Performance specifications/characteristics" included the physical specifications for the analyzer. Under "Relative Humidity" it stated "20 to 85%"; (3) The surveyor reviewed laboratory records from January 2019 through October 2020 and could not locate documentation to prove the humidity of the laboratory was being monitored. The laboratory director and laboratory manager stated to the surveyor on 11/02/2020 at 4:25 pm, the humidity in the laboratory was not being monitored.

D5435

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the urine centrifuge was functioning properly for 1 of 5 function checks. Findings include: (1) On 11/02/2020 at 11:00 am, the laboratory manager stated the following to the surveyor: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the McKesson variable speed centrifuge at a speed of 1750-2250 rpm (revolutions per minute) for 5 minutes; (c) Centrifuge speed and timer checks were performed every six months. (2) The surveyor reviewed the centrifuge maintenance records for 2019 and to date in 2020. There was no documentation the speed and timer had been checked for 1 of 4 entries as follows: (a) 03/17/2020 - Although the record showed the centrifuge had been cleaned, there was no documentation the speed and timer had been checked. (4) The surveyor reviewed the findings with the laboratory manager, who stated on 11/02/2020 at 2:15 pm, there was no documentation to prove the centrifuge speed and timer had been checked on 03/17/2020.

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP and failed to follow their policy for 4 of 4 test systems. Findings include: DIRECT SYPHILIS HEALTH CHECK (1) On 11/02/2020 at 11:15 am, the laboratory supervisor stated the following to the surveyor: (a) Syphilis Antibody Screen testing was performed using the Diagnostic Direct Syphilis Health Check test; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 04/05/2015). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) The surveyor reviewed the records with the laboratory manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. The laboratory manager stated to the surveyor on 11/02/2020 at 2:30 pm, the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. CEPHEID GENE XPRT (1) On 11/02/2020 at 11:15 am, the laboratory supervisor stated the following to the surveyor: (a) Chlamydia trachomatis and Neisseria gonorrhoea testing were performed using the Cepheid Gene Xpert analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 06/02/2014). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) The surveyor reviewed the records with the laboratory manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. The laboratory manager stated to the surveyor on 11/02/2020 at 2:30 pm, the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. MCKESSON CONSULT DIAGNOSTICS HCG COMBO (1) On 11/02/2020 at 11:15 am, the laboratory supervisor stated the following to the surveyor: (a) Qualitative Serum Pregnancy testing was performed using the McKesson Consult Diagnostics Combo test; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 05/09/2018). The document titled, "Consult Diagnostics hCG Combo Tests Cassette Quality Control Plan" under the heading "Quality Assessment" required a reassessment of the QCP at 6 month intervals; (3) The surveyor reviewed records and could not locate QA reviews every 6 months since the IQCP had been approved on 05/09/2018; (4) The surveyor reviewed the records with the laboratory manager and asked if there was documentation of QA reviews to evaluate the QCP every 6 months. The laboratory manager stated to the surveyor on 11/02/2020 at 2:30 pm, the QA reviews had not been performed every 6 months as stated in the policy. ALERE DETERMINE HIV 1/2 AG/AB COMBO (1) On 11/02/2020 at 11:15 am, the laboratory supervisor stated the following to the surveyor: (a) HIV (Human Immunodeficiency Virus) testing was performed using the Alere Determine HIV 1/2 Ag/Ab Combo test; (b) An IQCP (Individualized Quality Control

Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 12/18/2017). The document titled, "Alere Determine HIV-1/2 Ag/Ab Combo Quality Control (QC) Plan" under the heading "Quality Assessment" required a reassessment of the QCP at 6 month intervals; (3) The surveyor reviewed records and could not locate QA reviews every 6 months since the IQCP had been approved on 12/18/2017; (4) The surveyor reviewed the records with the laboratory manager and asked if there was documentation of QA reviews to evaluate the QCP every 6 months. The laboratory manager stated to the surveyor on 11/02/2020 at 2:30 pm, the QA reviews had not been performed every 6 months as stated in the policy.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be

acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager and laboratory director, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 3 of 4 competency evaluations performed. Findings include: (1) The surveyor reviewed records for 4 persons performing moderate complexity testing in 2018, 2019, and to date in 2020 (laboratory manager, who is also listed as testing person #1, testing person #2, testing person #3, and testing person #4). The records showed the evaluation for 3 of 4 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 03/06/2018, 03/07/2019, and 02/27/2020 evaluations had been performed by the laboratory manager/testing person #1 (this person had earned a Medical Laboratory Technician specialty by successfully completing a 52 week official military medical laboratory procedures course); (b) Testing Person #3 - The 03/07/2018, 03/07/2019, and 06/19/2020 evaluations had been performed by the laboratory manager/testing person #1; (c) Testing Person #4 - The 11/02/2020 evaluation had been performed by the laboratory manager/testing person #1. (2) The surveyor reviewed the records with the laboratory director and laboratory manager on 11/02/2020 at 1:05 pm, and explained that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory director and laboratory manager stated to the surveyor on 11/02/2020 at 1:20 pm, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.