

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0050874	(X3) Date Survey Completed 12/16/2021
Name of Provider or Supplier Osu University Health Services	Street Address, City, State 1202 West Farm Road, Stillwater, 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 12/13/2021 and 12/16/2021. The findings were reviewed with the laboratory director and testing person #1 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1409; D6033: Technical Consultant
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 director, the laboratory failed to follow the written clinical consultant competency policy based on the job responsibilities as listed in Subpart M for one of one clinical consultant. Findings include: (1) The surveyor reviewed personnel records for competency assessments performed during 2019, 2020 and 2021. There was no evidence competencies had been performed for the clinical consultant, based on job responsibilities; (2) The surveyor asked the laboratory director if a written policy to evaluate the clinical consultant, based on job responsibilities, was available and if competencies had been performed during the review period. The laboratory director stated to the surveyor on 12/13/2021 at 10:41 am, a policy to evaluate the technical consultant annually based on job responsibilities was written but had not been performed between 07/19/2019 and 12/13/2021.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of</p>

the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the testing person #1, the laboratory failed to follow the manufacturer's instructions for test timing for a qualitative solubility testing for three of 25 test reports. Findings include: (1) On 12/13/2021 at 09:50 am, testing person #1 stated to the surveyor: (a) The laboratory performed qualitative solubility testing using the Streck Sickledex test kit. (2) On 12/16/2021, the surveyor reviewed the manufacturer's instructions under the section titled, "Allow the sample to stand at room temperature (18C to 30C) for at least 6 minutes. Observe the sample for turbidity. Read results between 6 and 60 minutes." (3) On 12/16/2021, the surveyor then reviewed patient testing records from 01/01/2021 through 03/16/2021 and identified the following for three of 25 patient test reports: (a) Patient Report #1 - The collection date and time was on 01/14/2021 at 03:09 pm and approval date and time was on 01/14/2021 at 04:56 pm (one hour and 47 minutes later); (b) Patient Report #2 - The collection date and time was on 01/19/2021 at 02:38 pm and approval date and time was on 01/20/2021 at 10:44 am (20 hours and six minutes later); (c) Patient Report #3 - The collection date and time was on 03/16/2021 at 12:30 pm and approval date and time was on 03/16/2021 at 03:30 pm (three hours later). (4) The surveyor reviewed the findings with testing person #1. Testing person #1 stated on 12/16/2021 at 09:13 am, the laboratory could not prove the specimen was collected, tested, and read between 6 and 60 minutes as required by the manufacturer.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance procedures for the GeneXpert analyzer. Findings include: (1) On 12/13/2021 at 09:50 am, testing person #1 stated to the surveyor Chlamydia trachomatis and Neisseria gonorrhoeae testing were performed on the GeneXpert analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log. The weekly requirements were as follows: (a) Weekly (i) Power down the GeneXpert instrument and Computer (ii) Clean Fan Prefilter (3) The surveyor then reviewed maintenance records from 12/13/2019 through 11/11/2021. The weekly maintenance had not been documented as performed between: (a) 12/13/2019 and 01/29/2020 (b) 03/24/2020 and 04/17/2020 (c) 05/13/2020 and 05/29/2020 (d) 06/19/2020 and 07/01/2020 (e) 07/10/2020 and 08/03/2020 (f) 08/11/2020 and 10/19/2020 (g) 10/19/2020 and 11/18

/2020 (h) 11/30/2020 and 01/11/2021 (4) The surveyor reviewed the findings with the laboratory director. The laboratory director stated on 12/13/2021 at 03:56 pm the weekly maintenance had not been documented as performed as indicated above.

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 a review of records and interview with the laboratory director, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for six of 23 events. Findings include: (1) On 12/13/2021, the surveyor reviewed 2020 and 2021 proficiency testing events. For six of 23 events, the attestation statements had been signed approximately two to five months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Third 2020 Hematology Event - The sample testing had been completed on 11/09/2020, and the attestation statement had not been signed by the laboratory director/designee until 03/03/2021; (b) Second 2020 Microbiology Event - The sample testing had been completed on 06/23/2020, and the attestation statement had not been signed by the laboratory director/designee until 08/19/2020; (c) Third 2020 SARS- CoV-2 Event - The sample testing had been completed on 10/30/2020, and the attestation statement had not been signed by the laboratory director/designee until 03/31/2021; (d) First 2021 Chemistry Core Event - The sample testing had been completed on 01/26/2021, and the attestation statement had not been signed by the laboratory director/designee until 03/03/2021; (e) First 2021 Hematology Event - The sample testing had been completed on 03/25/2021, and the attestation statement had not been signed by the laboratory director/designee until 05/06/2021; (f) Second 2021 Immunology Event - The sample testing had been completed on 08/17/2021, and the attestation statement had not been signed by the laboratory director/designee until 10/07/2021. (2) The surveyor reviewed the findings with the laboratory director who stated on 12/13/2021 at 12:03 pm the attestations had been signed approximately two to five months after the proficiency samples had been tested. The surveyor explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.

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 director, 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 director, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for two of four competency evaluations performed. Findings include: (1) On 12/13/2021, the surveyor reviewed records for four persons performing moderate complexity testing in 2020 and to date in 2021 (12/13/2021). The records showed the evaluations for two of four persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 - The 03/11/2020 and 11/16/2021 evaluations had been performed by a testing person no longer employed in the laboratory (this person had earned an associate degree); (b) Testing Person #4 -

The 11/02/2020 evaluation had been performed by a testing person no longer employed in the laboratory (this person had earned an associate degree); (2) The surveyor reviewed the records with the laboratory director 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 stated to the surveyor on 12/13/2021 at 11:20 am, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.