

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382741	(X3) Date Survey Completed 06/26/2019
Name of Provider or Supplier Unitypoint Health-Grinnell Regional Medical Center	Street Address, City, State 210 Fourth Avenue, Grinnell, IA	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: A. Based on review of Avoximeter 4000 procedure, quality control (QC) records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 2:15 pm on 6/26/2019, the laboratory failed to perform the optical QC filters for the Avoximeter 4000 as established by the laboratory for one out of four weeks and one out of one day of patient testing in November 2018. The findings include: 1. On 11/12/2018, Patient identifier A had a carboxyhemoglobin performed using the Avoximeter 4000 analyzer. 2. The procedure for the Avoximeter 4000 analyzer states, "The optical QC filters (yellow and orange) will be analyzed each day of testing and weekly." 3. QC records indicated the laboratory performed the yellow optical QC filter on: 11/9/18, 11/23/18, and 11/30/18, and the orange optical filter on: 11/9/18, 11/16/18, 11/23/18, and 11/30/18. 4. The laboratory did not have documentation of the weekly yellow optical QC filter being performed from 11/9/18 - 11/23/18. 5. The laboratory did not have documentation of the yellow and orange optical QC filter being performed on 11/12/18 (the day of patient testing). 6. At the time of the survey, the laboratory did not have additional optical QC filter records from November 2018. 37401 B. Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records and confirmed by laboratory</p>

	<p>personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 06/26/2019, the laboratory failed to perform a positive and negative control each day of patient testing for the Alere Determine Human Immunodeficiency Virus (HIV) 1/2 test system. The findings include: 1. The laboratory performed QC with each new lot and shipment of test cartridges. 2. Laboratory personnel identifier #2 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the Alere Determine HIV 1/2 test system.</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 06/26/2019, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel performing arterial blood gas (ABG) testing received the appropriate training for three out of nine new testing personnel (identifiers #12, #13, and #17) hired since the last survey on 05/24/2017. At the time of the survey, the laboratory did not have training records available for laboratory personnel identifiers #12, #13, or #17.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 06/26/2019, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform moderate complexity testing as specified in standard D6065.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a</p>

chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 06/26/2019, the laboratory failed to have documentation to qualify three out of 17 testing personnel (identifiers #12- #14) who perform moderate complexity testing.