

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2069529	(X3) Date Survey Completed 02/27/2018
Name of Provider or Supplier Heritage Medical Associates	Street Address, City, State 920 S Hartmann Drive Suite 200, Lebanon, TN	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the throat cultures for the specialty bacteriology proficiency testing (PT) attestation records in 2016-17 and an interview with the primary testing person determined the laboratory director failed to ensure that all PT attestation statements are signed during 2016 and 2017. The findings include: 1. Review of the 2016 1st-3rd events and 2017 1st-3rd events PT records for throat cultures for the specialty bacteriology revealed the laboratory director did not sign the attestation statements for testing persons during the 2016 1st-2nd events and 2017 1st, 2nd, and 3rd events. 2. Interview with the primary testing person on February 27, 2018, at approximately 9:50 AM confirmed that the director failed to attest/sign attestation statements during the 1st-2nd events and 2017 1st, 2nd, and 3rd events..</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including</p>

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 the May 17 through December 5, 2016 throat cultures for the specialty bacteriology quality control (QC) records and interview with lead testing person, the laboratory failed to maintain the bacteriology QC printouts for the throat cultures: media lot and expiration dates, Taxo A disc lot and expiration dates, positive control ATCC lot and expiration dates for 2016. The findings include: 1) Review of the May 17 through December 5, 2016 throat cultures for the quality control (QC) records the bacteriology QC for throat cultures: media lot and expiration dates, Taxo A disc lot and expiration dates, positive control ATCC lot and expiration dates for 2016. 2) Interview with primary testing person at approximately 2:30 p.m. on February 27, 2018 confirmed missing the May 17 through December 5, 2016 throat cultures for the quality control (QC) records the bacteriology QC for throat cultures: media lot and expiration dates, Taxo A disc lot and expiration dates, positive control ATCC lot and expiration dates for 2016.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the throat cultures for the specialty bacteriology proficiency testing (PT) performance summary records and interview with testing personnel number one determined the laboratory director failed to ensure the PT performance summary records were reviewed in 2016 and 2017. The findings include: 1) Review of the throat cultures for the specialty bacteriology PT performance summary records for 1st-3rd events of 2016-2017 revealed the laboratory director's missing signature on all 6 of 6 events performance summary records in 2016 and 2017. 2) Interview on February 27, 2018 at 11:00 a.m. with testing personnel number one confirmed the throat cultures for the specialty bacteriology PT performance summary records for 1st-3rd events of 2016-2017 revealed the laboratory director's missing signature on all 6 of 6 events performance summary records in 2016 and 2017.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on the lack of 3 of 3 testing personnel competency documents for performing throat cultures for the specialty bacteriology and upon interview with the primary testing person, determined the technical consultant failed to ensure documented annual competency evaluations of testing personnel for 2016-2017. The findings include: 1. There were no competency evaluations reviewed/signed for 3 of 3 testing personnel in 2016-17 for performance of throat cultures for the specialty bacteriology testing. 2. Upon interview with the primary testing person at approximately 2:30 p.m. on February 27, 2018, confirmed the Technical Consultant failed to document/sign competency assessments for 3 of 3 testing persons in 2016-17 for throat cultures for the specialty bacteriology testing.