

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0677943	(X3) Date Survey Completed 08/01/2019
Name of Provider or Supplier Central Mississippi Health Services	Street Address, City, State 1134 Winter St, Jackson, MS	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient complete blood count (CBC) results in electronic medical records, interview with the testing personnel, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 8-1-19 at 1:45 p.m., and lack of documentation of patient CBC results since the last survey on 7-19-17, the laboratory failed to retain documentation of patient CBC results from the Horiba Medical ABX Micros 60 hematology analyzer, that is transcribed into electronic medical records, for at least two years. Findings include: Review of electronic medical records revealed patient CBC results are manually entered into the patient electronic medical records from the Horiba Medical ABX Micros 60 hematology analyzer printouts. On the day of the survey, 8-1-19, there was no documentation of patient CBC results, that were transcribed into electronic medical records, since 7-19-17. The testing personnel stated on 8-1-16 at 1:45 p.m. that CBC results from the hematology analyzer are not retained after the results are entered in the patient electronic medical records.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on review of quality control (QC) records for the Horiba Medical ABX Micros 60 hematology analyzer from 2-1-18 through 5-29-19 and patient electronic medical records, the laboratory failed to include at least two levels of control material for complete blood count (CBC) testing on 8-22-18, when two patient CBC tests were performed and reported. Findings include: Review of QC records for the Horiba Medical ABX Micros 60 hematology analyzer from 2-1-18 through 5-29-19 and patient electronic medical records revealed no documentation of performance of at least two levels of control on 8-22-18, when CBC testing was performed and results reported on Patient #110673 and #81083.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

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

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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:
Based on review of the Centers for Medicare and Medicaid Services (CMS) data system for proficiency testing, the laboratory's proficiency testing (PT) records since the last survey on 7-19-17, and interview on 8-1-19 at 10:30 a.m. with the technical consultant, the laboratory director failed to ensure that the laboratory enrolled in an HHS approved proficiency testing program for complete blood count (CBC) testing for the three PT events of 2018. Findings include: Review of the CMS data system for proficiency testing and the laboratory's PT records since the last survey on 7-19-17 revealed no documentation of the performance of proficiency testing for the three events of 2018. In an interview on 8-1-19 at 10:30 a.m., the technical consultant confirmed the laboratory was not enrolled in PT for CBC testing for the three events of 2018.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on the CMS data system for proficiency testing, review of proficiency testing (PT) records since the last survey on 7-19-17, and lack of documentation of corrective action, the laboratory director failed to ensure that an approved corrective action plan was followed when proficiency testing results for the specialty of hematology were

found to be unsatisfactory for the first PT event of 2019. Findings include: Review of the CMS data system for proficiency testing and PT records since the last survey on 7-19-17 revealed an unsatisfactory score of 64% for the specialty of hematology for Event 1 of 2019, with no documentation of corrective action.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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.

This STANDARD is not met as evidenced by:
Based on review of personnel records, patient complete blood count (CBC) test reports, lack of documentation of training, and interview with the technical consultant on 8-1-19 at 2:00 p.m., the laboratory director failed to ensure the testing personnel, who performed patient testing on 8-22-18, received appropriate training or demonstrated that they could perform all testing operations reliably to provide and report accurate CBC test results with the Horiba Medical ABX Micros 60 hematology analyzer, prior to testing patient specimens. Findings include: Review of personnel records revealed no documentation of training on the Horiba Medical ABX Micros 60 hematology analyzer for the individual who performed patient testing on 8-22-18. Review of patient CBC test reports revealed this individual performed and reported, in the electronic medical record, CBC results for Patient #110673 and #81083 on 8-22-18. The technical consultant confirmed on 8-1-19 at 2:00 p.m. that there was no training documented for this individual or evaluation of competency to ensure they could perform all testing operations reliably to provide and report accurate CBC test results.