

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0670151	(X3) Date Survey Completed 02/24/2020
Name of Provider or Supplier Mid-South Internal Medicine Specialist Pc	Street Address, City, State 7550 Wolf River Blvd Suite 102, Germantown, 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
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 the laboratory's maintenance records and quality control (QC) records for the Tosoh G8 glycated hemoglobin (Hgb A1c) instrument, and interview with the laboratory liaison, the laboratory failed to retain the identity of persons performing maintenance and quality control, and quality control lot numbers in 2019 and 2020 for the Tosoh G8 instrument. The findings include: 1) Review of the laboratory's maintenance and QC records for the Tosoh G8 Hgb A1c instrument revealed the following: Maintenance log for December 2019: No identity of the person /persons who performed the daily maintenance. Quality control records for December 16 through December 18, 2019 and January 9 through January 13, 2020: No identity of the person who performed the quality control; no record of QC lot number. 2) Interview with the laboratory liaison on February 24, 2020 at 2:45 pm confirmed the laboratory failed to retain all analytic records for the Tosoh G8 Hgb A1c instrument in 2019 and 2020.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the</p>

laboratory liaison, the laboratory failed to retain proficiency testing records for two years for testing events 2018 event three for hematology and 2019 event two for miscellaneous chemistry. The findings include: 1) Review of the laboratory proficiency testing records obtained from the laboratory's proficiency testing program revealed the following: 2018 event three hematology performance evaluation report was available 12.20.2018. 2019 event two miscellaneous chemistry performance evaluation report was available 11.21.2019. 2) Review of the laboratory's onsite proficiency testing records revealed the following: No performance evaluation report for 2018 event three hematology. No proficiency testing records for 2019 event two for miscellaneous chemistry. 3) Interview with the laboratory liaison on February 24, 2020 at 2:45 pm confirmed the laboratory failed to retain all proficiency testing records in 2018 and 2019.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of the laboratory's procedure manual, testing personnel records and interview with the laboratory liaison, the technical consultant failed to ensure all testing personnel were trained for the use of new instruments in 2018 and 2019. The findings include: 1) Observation of the laboratory on February 24, 2020 at 8:30 a.m. revealed the Tosoh G8 in use for patient testing for glycated hemoglobin (Hgb A1c) and the Medonic M series instrument in use for patient testing for complete blood count instrument (CBC). Both instruments were new since the last survey date. Use of the Medonic M series began in 2018; the Tosoh G8 was placed into use in 2019. 2) Review of the laboratory's procedure manual quality assurance plan revealed that personnel would be properly trained in the use of any new instrument before patient samples are tested. 3) Review of the laboratory procedure manual revealed training and education is the responsibility of the technical consultant. 4) Review of testing personnel records revealed no documented training for testing personnel number three for use of the Tosoh G8 Hgb A1c instrument, and testing personnel numbers three and four for the use of the Medonic M series CBC instrument. 5) Interview with the laboratory liaison on February 24, 2020 at 2:45 p.m. confirmed the technical consultant failed to ensure training for the use of new instruments for testing personnel numbers three and four in 2018 and 2019.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on review of patient test reports and instrument logs for the Medonic M series complete blood count (CBC) instrument, the laboratory procedure manual, and

interview the laboratory liaison, testing personnel failed to follow laboratory policy for quality control in 2019 when testing personnel performed and reported patient number ten prior to performing quality control. The findings include: 1) Review of patient number ten test report and the daily instrument log for the Medonic M series CBC instrument revealed patient testing performed prior to performance of quality control as follows: Patient number ten performed and reported at 9:30 am on 01.31.2019; quality control performed at 2:00 pm. 2) Review of the laboratory procedure manual revealed that at least two levels of quality control must be performed and acceptable before patient testing can be performed. 3) Interview with the laboratory liaison on February 24, 2020 at 2:45 pm confirmed testing personnel failed to ensure quality control was acceptable prior to reporting patient CBC results in 2019.