Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1038982	12/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Medical Specialists Of Texarkana	1002 Texas Blvd Suite 201, Texarkana, TX	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions for storage of 1 of 1 boxes of Hemoccult ICT controls. The findings included: 1. Surveyor observation on December 1, 2021 at 8:50 hours in the storage room refrigerator found 1 box of Hemoccult ICT controls. Lot #M101127 Expiration date: 07-31-2022 2. Review of manufacturer's instructions for the Hemoccult ICT controls under "Storage and Stability" stated, "Store product at controlled room temperature 15 to 30 degrees Celsius; DO NOT FREEZE." 3. The laboratory was asked to provide documentation of following the manufacturer's instructions for storage of the controls. No documentation was provided. 4. Interview with the office manager and the technical consultant on December 1, 2021 at 11:30 hours in the storage room confirmed the findings. II. Based on review of laboratory personnel records, review of manufacturer's instructions, and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of following the manufacturer's instructions for ensuring testing personnel were trained to perform Covid 19 testing on the BD Veritor prior to patient testing for 2 of 2 testing personnel. The findings included: 1. Review of the laboratory's personnel files for testing personnel 1 and testing personnel 2 (as listed on Form CMS-209) found no documentation of training for the BD Veritor used by the laboratory to perform Covid 19 patient testing. 2. Review of the manufacturer's instructions for the BD Veritor authorized for Emergency Use Authorization for Covid 19 testing under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY, it stated, "All

	operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to ensure testing personnel are trained prior to testing patients on the BD Veritor for Covid 19 testing. No documentation was provided. 4. Interview with the office manager and the technical consultant on December 1, 2021 at 11:30 hours in the storage room confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policies, and confirmed in interview of laboratory personnel, the laboratory did not have a policy to address flags on the Abbott Cell Dyn Emerald analyzer installed in May 2019. The findings included: 1. Surveyor observation on December 1, 2021 at 08:50 hours in the laboratory found the laboratory had installed an Abbott Cell Dyn Emerald in May 2019 (serial #7349). 2. Review of the laboratory's policies found the laboratory did not have a current policy for testing personnel to follow when flags on patient samples for CBCs arise for the Cell Dyn Emerald. The policy found in the manual was for the D3 hematology analyzer which was no longer in use by the laboratory. 3. The laboratory was asked to provide documentation of a policy for testing personnel to follow when flags on patient CBCs arise. No documentation was provided. 4. Interview with the office manager and the technical consultant on December 1, 2021 at 11:30 hours in the storage room confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's verification studies on the Abbott Cell Dyn Emerald, and staff interview, the laboratory failed to have documentation of verifying 1 of 1 patient normal values currently in use. The findings included: 1. A review of the laboratory's procedures for the Abbott Cell Dyn Emerald hematology analyzer revealed the laboratory defined patient normal values for 1 samples type used for males and females Complete Blood Cell Count (CBC). 2. A review of the laboratory's verification studies performed on the Abbott Cell Dyn

	Emerald (placed into use on in May 2019) found the laboratory did not have a complete patient normal range study. 3. The laboratory was asked to provide documentation of verifying the identified patient normal values. No documentation was provided. 4. Interview with the office manager and the technical consultant on December 1, 2021 at 11:30 hours in the storage room confirmed the findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory verification studies performed on the Abbott Cell Dyn Emerald hematology analyzer installed in May 2019, and staff interview, the laboratory director failed to document her review of the studies to assess their acceptability. The findings included: 1. A review of the laboratory's verification studies performed the Abbott Cell Dyn Emerald (serial #7349) installed in May 2019 found the laboratory director failed to document his review of the studies to assess their acceptability. 2. The laboratory was asked to provide documentation of the review of the studies for acceptability. No documentation was provided. 3. Interview with the office manager and the technical consultant on December 1, 2021 at 11:30 hours in the storage room confirmed the findings.