Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0973051	11/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Chitra Venkatraman Md Pa	7300 Hanover Drive, Suite 301, Greenbelt, MD	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical consultant (TC), the laboratory did not ensure that all the testing personnel who tested patient samples perform the PT. Findings: 1. The laboratory currently has 2 testing personnel listed on the "Laboratory Personnel Report (CMS-209)." During an interview at 10:15 AM on the day of the survey the office manager stated that they also perform patient testing when the other TP are not able to. 2. A review of hematology/coagulation PT attestation worksheets from 2020 and 2021 showed that PT was not performed by the office manager for 5 of 5 events. 3. During an interview on 11/12/2021 at 1:30 PM, the TC confirmed that PT samples are not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the technical

	consultant (TC), the laboratory failed to ensure that the laboratory director (LD) and testing personnel (TP) sign the PT attestation statements, attesting to the routine integration of the samples into the patient workload using the laboratory's routine methods. Findings: 1. A review of hematology PT records from 2020 to 2021 showed that for 1 of 5 events the office manager filled in the names of the LD and TP. The LD and TP did not sign the attestation statement, attesting that PT specimens were run in the same way as patient samples. 2. This was confirmed by the TC during an interview on 11/12/2021 at 1:30 PM.
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: I. Based on laboratory procedure manual and record review and interview with the testing personnel (TP) and technical consultant (TC), the laboratory did not ensure that written procedures for performing laboratory testing are followed by the laboratory TP. Findings: 1. The procedure, "Manual Review" states that "All testing personnel must possess adequate knowledge to process specimens, perform testing, adhere to CLIA, OSHA safety rules and regulations, and report test results" and "Laboratory Personnel must document review of this manual by signing below." 2. Review of the signatures of TP on the document showed that 1 of 3 TP performing testing as of the day of the survey did not sign the "Manual Review" sheet to show that they had reviewed the laboratory's procedure manual. 3. The procedure, "Material Management" states to "Document on the Reagent Inventory Log for each section the following: a. Date item was received, b. Name of item, c. Quantity received, d. Lot number, e. Expiration date, f. Date opened (Once item is opened), and g. Date expired once opened if different from shelf life expiration date (expiration date may be adjusted once opened/ refer to package insert for stability once opened)." 4. Record review showed that there were no "Reagent Inventory Logs" present at the time of the survey. TP #1 stated that the laboratory did not document reagents and controls on the "Reagent Inventory Log." 5. The procedure "Specimen Collection, Handling and Transport; Patient Test Management" states under "General Handling of Anticoagulated Specimens", "EDTA Specimens" that "Samples are mixed on the hematology rocker while awaiting analysis in the laboratory." The "Sysmex" procedure states, "Do not place samples on a mechanical rocker. Constant rocking may alter white cell membranes, which may result in inappropriate flagging." 6. During an interview at 10:15 AM on the day of the survey TP #1 stated that patient specimens drawn into EDTA tubes are placed on the mechanical rocker if the Medical Assistant is not immediately available to run them on the hematology analyzer. 7. During an interview on 11/12/2021 at 1:30 PM the TC confirmed that the laboratory did not ensure that written procedures for performing laboratory testing were followed by the laboratory TP. II. Based on laboratory procedure manual and record review and interview with the testing personnel (TP) and technical consultant (TC), the laboratory did not ensure that written procedures for performing parallel testing of new hematology controls accurately reflect the current practice in the laboratory. Findings: 1. The procedure "Quality Control and Assessment", "Procedure for Change in Lot of Control Material (Sysmex XP-300)" states "Run each level of new control material 5

	times over 5 days using more than one operator." The "Sysmex" procedure, subheading "Starting a New Lot of Controls" states "Parallel test new controls by analyzing the three levels of controls a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated and values are running within assay ranges, the lot may be placed into production." 2. During an interview at 10:15 AM the TP stated that they perform parallel testing of new and old lot numbers of hematology controls "2-3 days before" starting the new lot number. 3. Quality assurance record review showed that on the "Quality Assessment Plan" "Monthly Checklist" for June 2021 the TC documented that the hematology controls "Lots 11380710, 711, 712 Exp. 8.25.21 in use 6/2-30/21" were "Not Parallel Tested." 4. A review of quality control records from 03/01/2021 to 10/31/2021 showed that the "new" lot of hematology controls (lot # 10540710, 10540711, 10540712) was tested in parallel with the "old" lot of controls a total of 4 times from 03/05/2021 to 03/10/2021. 5. During an interview on 11/12/2021 at 1:30 PM the TC confirmed that the laboratory's procedures for performing parallel testing of hematology controls are not consistent and do not reflect the current practice in the laboratory.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: The laboratory did not follow the manufacturer's instructions for performing parallel testing of new hematology controls. Cross-refer to D5401, part II.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, procedure manual and manufacturer instructions review, and interview with the technical consultant (TC), the laboratory did not ensure that hematology controls and reagents are labeled with their opened and expiration dates. Findings: 1. The laboratory runs "Eightcheck-3WP/X-Tra" controls on their Sysmex XP-300 hematology analyzer. A review of manufacturer instructions showed that the hematology controls expire 14 days after opening. 2. During a tour of the laboratory at 10:15 AM, it was observed that the opened and in use hematology controls in the laboratory refrigerator were not labeled with the date that they were put in to use. The controls were in a cup labeled with the manufacturer's expiration date for unopened controls. The cup was not labeled with the opened date or new opened expiration date for the controls. 3. The "Sysmex" procedure manual under "III. Supplies and

	Reagents" states that the "CELLPACK Stability" is "Opened, CELLPACK is stable for 60 days" and the "STROMATOLYSER-WH Stability" is "Opened, STROMATOLYSER-WH is stable for 90 days." These reagents are used on the Sysmex XP-300 hematology analyzer. 4. It was observed at 10:15 AM that the in-use "CELLPACK" reagent (lot # Y1071/expiration date: 01/18/2023) and the in-use "STROMATOLYSER-WH" reagent (lot # Y1002/expiration date 04/29/2022) were labeled with an opened date of 11/08/2021. The reagents were not labeled with their new opened expiration dates. 5. During an interview on 11/12/2021 at 1:30 PM, the TC confirmed that the in-use hematology controls and reagents were not labeled with their opened and expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on laboratory record and procedure manual review and interview with the technical consultant (TC), the laboratory failed to ensure that the lot numbers and expiration dates of reagents used for hematology testing are documented. Findings: 1. The laboratory performs hematology testing on a Sysmex XP-300 hematology analyzer. The laboratory did not document the new opened expiration date of the hematology reagents used on the analyzer. Cross-refer to D5415. 2. The "Sysmex" procedure manual under "III. Supplies and Reagents" states that the "CELLPACK Stability" is "Opened, CELLPACK is stable for 60 days." A review of "CELLPACK" reagent records on the hematology analyzer from June through November, 2021 showed that the hematology analyzer records the lot number and manufacturer's expiration date of the unopened reagent once it is loaded onto the analyzer, but it does not update the expiration date to reflect the new opened expiration date. 3. Record review showed that the laboratory did not utilize the "Reagent Log" provided in the laboratory's procedure manual. Cross-refer to D5401. 4. During an interview on 11/12 /2021 at 1:30 PM, the TC confirmed that the documentation of lot numbers and expiration dates of reagents used for hematology testing was incomplete.
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 record review and interview with the testing personnel (TP) and technical consultant (TC), the TC failed to ensure that each individual performing tests receives training and education appropriate for the type and complexity of the laboratory services performed. Findings: 1. The laboratory currently has 2 TP listed on the "Laboratory Personnel Report (CMS-209)." During an interview at 10:15 AM on the day of the survey the office manager stated that they also perform patient testing when

	the other TP are not able to. 2. A review of training records showed that there was no documentation that the office manager was trained to perform hematology testing on the Sysmex XP-300 hematology analyzer. 3. During an interview on 11/12/2021 at 1: 30 PM the TC confirmed that the appropriate training was not performed on all staff who perform patient testing.
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 record review and interview with the testing personnel (TP) and technical consultant (TC), the TC failed to perform and document the competency reviews on all TP. Findings: 1. The laboratory currently has 2 TP listed on the "Laboratory Personnel Report (CMS-209)." During an interview at 10:15 AM on the day of the survey the office manager stated that they also perform patient testing when the other TP are not able to. 2. A review of competency assessment records from 2020 and 2021 showed that there was no documentation of competency assessments performed on the office manager. 3. During an interview on 11/12/2021 at 1:30 PM the TC confirmed that competency reviews were not performed on all staff who perform patient testing.