Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0926884	09/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Medstar Shah Medical Group Philip J Bean Med Ctr	24035 Three Notch Road, Hollywood, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency test records and interview with the laboratory technical consultant the laboratory did not document corrective actions and monitoring of corrective actions when proficiency test results showed unsuccessful test scores. Findings: 1. The laboratory obtained a test score of 60% for the sodium analyte on the third proficiency test event of 2022 (MLE M3 2022), and the laboratory corrective action was to make sure that their will be no outliers on the next survey. The corrective action did not state how the laboratory would accomplish this or if the laboratory's investigation showed that only monitoring would be needed, there was no description by the laboratory for monitoring procedural changes if any were made. 2. The laboratory obtained a test score of 50% for the CRP (C-reactive protein) analyte on the proficiency test event identified as MLE M1 2023 because the laboratory reported the test results to the proficiency test provide in mg/l instead of mg/dl. The corrective action stated that the laboratory will pass the next proficiency test event. The corrective action did not state that the laboratory will make sure that the correct units of measurement would be used for reporting the proficiency test results and did not state who will be responsible for monitoring this. 3. This was confirmed with the technical consultant during interview on the afternoon of the day of the survey.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when

	appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the procedure manual, review of the manufacturer's instructions for use (IFU), and interview with the technical consultant (TC), the laboratory failed to follow the lactate dehydrogenase (LDH) procedure by testing specimens stored at refrigerated temperatures when stability was only established for specimens stored at room temperature. Findings: 1. The laboratory's procedure and the IFU for LDH both stated that "Separated serum/plasma samples are stable for 3 days at 20-25C. Do not refrigerate or freeze." 2. The specimen transportation policy stated that each of the collection sites "will place their specimen in the refrigerator" and the courier will pick up specimens from the collection sites "with specimen transportation cooler with the ice pack in it." 3. The specimen stability chart stated that LDH was "Stable up to Day 2" when "specimens are stored at 2-8C." 4. During the survey on 09/28/2023 at 11:34 AM, the TC confirmed that the procedure and IFU stated that specimens for LDH tested should not be refrigerated and that all specimens tested by the laboratory for LDH were stored and transported at refrigerated temperatures.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final reports and interview with the technical consultant (TC), the laboratory failed to ensure that the final test report included the normal reference range values for the interpretation of the patient test results that were listed in the "Reference & Critical Lab Result for MedStar Shah LAB" procedure. Findings: 1. The "Reference & Critical Lab Result for MedStar Shah LAB" procedure listed five different normal patient ranges for white blood count (WBC) depending on the age of the patient. The laboratory information system (LIS) listed seven different WBC ranges with different normal reference ranges. 2. The normal WBC ranges listed in the procedure manual were for patients aged 3D[day]-3M[month], 3M-6M, 6M-6Y [year], 6Y-12Y, and >12Y. Normal WBC ranges listed in the LIS were for patients aged 0-1D, 1D-1M, 1M-1Y, 1Y-4Y, 4Y-8Y, 8Y-13Y, and 13Y-150Y. 3. The "Reference & Critical Lab Result for MedStar Shah LAB" procedure listed five different normal patient ranges for mean corpuscular volume (MCV) depending on the age and sex of the patient. The LIS listed five different normal reference ranges for all patients. 4. The normal MCV ranges listed in the procedure manual were for patients aged 1D-5Y, 5Y-6Y, 6Y-12Y, 12Y-18Y, and >18Y. Normal MCV values listed LIS were for patients aged 1D-6M, 6M-6Y, 6Y-12Y, 12Y-18Y, and 18Y-150Y. 5. During the survey on 09/28/2023 at 3:40 PM, the TC confirmed that the

	hematology analyzer failed to provide an accurate normal reference range values as defined in the " Reference & Critical Lab Result for MedStar Shah LAB" procedure manual.