Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1055495	11/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Shamra Medical Laboratory, Llc	950 State Route 35, Middletown, NJ	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for the 2nd Chemistry event of 2025 . The finding includes: 1. The laboratory did not evaluate "Not Graded 9", from API in event 2, 2025 for the following: a) Bilirubin, Total (mg/dL) samples CH-07, 09, and 10. 2. The TC confirmed on at 10:30 am on 11/19/25 that the laboratory failed to evaluate the above mentioned coded results.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy of Total Bilirubin (TBIL) results obtained from the American Proficiency Institute (API) for the Chemistry-Core 2nd event of 2025. The findings include: 1. The laboratory

	received a score of 100%, but received a code "9" for Total Bilirubin samples CH-07, 09 and 10. 2. API reported the range for TBIL sample CH-07 as 1.8 - 2.9 mg/dL. 3. The laboratory reported TBIL Sample CH-07 as out of range with 1.2 mg/dL. 4. API reported the range for TBIL sample CH-09 as 1.3 - 2.2 mg/dL . 5. The laboratory reported TBIL Sample CH-09 as out of range with 1.1 mg/dL. 6. API reported the range for TBIL sample CH-10 as 2.4 - 3.7 mg/d . 7. The laboratory reported TBIL Sample CH-10 as out of range with 1.7 mg/dL. 8. The laboratory obtained a 40% for TBIL 2nd event of 2025 with API. 9. The TC confirmed on 11/19/25 at 10:20 am, the accuracy of the PT results were not verified.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: A) Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) and interview with the Technical Consultant (TC), the laboratory failed to follow the procedure "Quality Control" for the Cobas Integra 400 plus analyzer used to perform Routine Chemistry testing from 6/1/25 to 11/19/25 . The findings include: 1. The PM stated "18. The laboratory director or Technical consultant will review and sign the QC logs each month." 2. There was no documented evidence that the above mentioned procedure was performed in June of 2025. 3. The TC confirmed on 11/19 /25 at 10:55 am the laboratory failed to follow the above mentioned procedure. B) Based on surveyor review of the PM, Quality Control Validation (QCV) and interview with the TC, the laboratory failed to follow the procedure "Control Validation" for the cobas integra 400, plus analyzer used to perform Routine Chemistry, CLA-1 Luminometer used to perform specific IgE testing in from 12/17 /21 to 11/19/2025. The findings include: 1. The PM stated as follows: a) "2. Check the values of the new QC against the manufacturer's expected ranges" b) "5. Document the date put into use on the package insert" 2. There was no documented evidence that the above mentioned procedures were performed. 3. The TC confirmed on 11/19/25 at 10:50, am the laboratory failed to follow the above mentioned procedures. C) Based on surveyor review of the Procedure Manual (PM), and interview with the Technical consultant (TC), the laboratory failed to have a procedure for verifying the accuracy of unregulated testing at least two times each year from June 2022 to 11/19/2025. The findings include: 1. The laboratory performs unregulated specific IgE on the CLA-1 Luminometer analyzer. 2. There was no procedure for verifying the accuracy of specific IgE testing at least two times each year. 3. The TC confirmed on 11/19/25 at 11:55 am, the laboratory failed to have available the above mentioned procedure. 48354 D) Based on surveyor review of the PM, QCV procedures and interview with the TC, the laboratory failed to follow the procedure "Control Validation" for the Abbott Cell Dyn analyzer for Hematology testing from 10/17/24 to 11/20/2025. The findings include: 1. The QCV procedure stated the following: a) "document the date put into use on the package insert." b) "initial or sign document who performed the control validation." 2. There were no dates the verified quality control materials were put into use for lot #'s 5230, 5146, 5062, 4344, and 4288. 3. There were no signatures on the QCV records for lot 5062. 4. The TC confirmed on 11/20/25 at 1:45 am, the laboratory failed to follow the QCV procedure.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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: A) Based on surveyor observation of reagents, review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to discard expired reagents used for Chemistry testing from 11/30/22 to 11/20/25. The findings include: 1. Surveyor observation of the reagents revealed the following to be expired: a) One unopened vial of Precinorm Uplus 1, lot # 45946201 expired on 11/30/22. b) One uponed vial of Precinorm Uplus 2, lot # 45946201 expired on 11/30/22. 2. The TC confirmed on 11/20/25 at 1:20 pm, the laboratory failed to discard expired reagents. B) Based on surveyor observation of Quality Control (QC) material in use, review of the Control Kits Manufacturers Package Insert (MPI) and interview with the Technical Consultant (TC), the laboratory used unstable QC material and failed to put correct expiration dates for routine Chemistry and Endocrinology tests from 2/1/24 to 4/3/25. The findings include: 1. The expiration date of the Precicontrol (PC) QC material shortens once reconstituted. 2. The MPI stated Parathyroid hormone (PTH) had a 3 day stability once reconsituted. a) PC Thyro 1 lot # 80574299, had a reconstituted date of 10/26/25. b) PC Thyro 2 lot #80574399, had a reconstituted date of 10/26/25. 3. The MPI stated Tumor Marker (TM) had a 2 week stability once reconsituted. a) PC TM 1 lot # 77723690, had a reconstituted date of 10/26/25. b) PC TM 2 lot # 77723790, had a reconstituted date of 10/26/25 4. The MPI stated Multi Marker (MM) had a 72 hour stability once reconsituted. a) PC MM 1 lot # 77744299, had a reconstituted date of 11/11/25. b) PC MM 2 lot # 77744499, had a reconstituted date of 11/11/25 5. Approximately 26 patients were run and reported with unstable quality control material. 6. The TC confirmed on 11/20/25 at 11:45 am, the laboratory used unstable quality control material.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for periodically verifying the accuracy of calculated data by the Lab Information System (LIS) from 4/1/24 to 11/20/25. The finding includes. 1. The laboratory did not have a procedure for verifying Estimated Glomular Filtration Rate (eGFR) calculations by the LIS. 2. The TC confirmed on 11/20/25 at 2:00 pm, the laboratory did not verify the accuracy of calculated data by the LIS.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on the lack of Performance Specification (PS) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that PS was performed on CLA-1 Luminometer for specific IgE from June 2022 to 11/19/25. The findings include: 1) There was no documented evidence the laboratory verified the CLA-1 Luminometer prior to patient testing. 2) The TC confirmed on 11/19/2025 at 1: 00 pm, there were no PS records for the CLA-1 Luminometer.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (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 surveyor review of Testing Personnel (TP) files and interview with Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that all TP had appropriate training documentation from 9/24/25 to 11/20/25. The findings include: 1. The intial training records for TP #3 as listed on the CMS 209 form had no signatures of approval by the director or trainer. 2. There were no dates of completion on the training records for TP #3. 3. The records did not state who trained TP #3. 4. The TC confirmed on 11/20/25 at 1:40 pm, the LD failed to ensure all TP had the appropriate training records.