Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1055495	12/17/2021
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 Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from the American Proficiency Institute (API) for Immunology, Chemistry and endocrinology events performed in 2020 and 2021. The findings include: 1. The laboratory did not evaluate "Not Graded" response from API for the following: a. SARS-CoV-2 IgM Sample SAB-2, 2nd event 2020 b. Adrenocorticotropic Hormone (ACTH) sample IAS-06 2nd event 2021 c. Folate sample IA-07, 2nd Event 2021 d. Folate sample IA-01, 3rd event 2021 2. The TP #2 listed on CMS form 209 confirmed on 12/16/21 at 10:00 am 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 Testing Personnel (TP), the laboratory failed to verify the accuracy of chemistry, endocrinology, and Immunology test results obtained from the American Proficiency Institute (API) from January 2020 to the date of survey. The findings include: 1. The laboratory received a score of 100 but results were not graded. 2. There was no documented evidence the laboratory verified: a. SARS-CoV-2 IgM 2nd event 2020 b. Adrenocorticotropic Hormone (ACTH) 2nd event 2021 c. Folate sample 2nd and 3rd Event 2021 3. The TP #2 listed on CMS form 209 confirmed on 12/16/21 at 10:00 am accuracy of the PT results were not verified
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of Laboratory records and interview with the Testing Personnel, the laboratory failed to meet the analytic system requirements to provide quality testing at the from 6/19/21 to the date of survey survey. 1. The laboratory failed to review and evaluate Proficecy Test results. Cross refer D5211. 2. The laboratory failed to verify the accuracy of chemistry, endocrinology, and Immunology tests. Cross refer D5215. 3. The laboratory failed to follow the Operators Manual for "Pre-Calibration Procedures". Cross refer to D5411. 4. The laboratory retained expired Quality Control (QC) and Reganet Packs. Cross refer to D5417. 5. The laboratory failed to perform and document Calibration procedures at least once every six months. Cross refer D5437 6. The laboratory failed to perform and document QC on each day of patient testing. Cross refer D5445 7. The laboratory failed to take corrective action when one out of two levels of controls were out of range. Cross refer 5783. 8. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Cross refer D5491
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 review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their policy for "Patient Test Management - Test Record/Accession Logs" (PTM) from 6/12/19 to the date of survey. The findings include: 1. The PTM policy required that "All specimens and tests ordered will be logged into an accession log (patient test log) or entered into a computer (if applicable) upon receipt in the laboratory" 2. The PTM policy required

	that the "Accession log contains the following information": a. Name of laboratory b. Specimen date c. Time of collection and time of receipt in laboratory (if different) d. Fasting/non-fasting e. Patient name and/or identification number f. Patient age (optional unless relevant to test) g. Patient sex (optional unless relevant to test) h. Physician ordering test(s) i. Test(s) ordered j. Unacceptable specimen condition k. Date test was performed l. Test(s) result(s) (optional if another method of back up results is used) m. Initials of person running test/enter result n. Any pertinent clinical information. 3. The The TP#2 listed on CMS from 209 confirmed on 12/17/2021 at 10: 21 am the aforementioned policy were not followed.
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: Based on surveyor review of the Operators Manual (OM), and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for "Pre-Calibration Procedures" from 5/15/20 to the date of survey. The findings include: 1. The OM stated to "Pre-Calibration Procedures ensure proper instrument performance and a successful calibration. These steps should be completed just before starting the CELL-DYN Emerald calibration process. If problems are detected during these checks, do not attempt to calibrate the instrument. After the problems have been resolved, repeat the Pre-Calibration Procedures to verify proper instrument performance. A Pre-Calibration Procedures Checklist is provided in Appendix E: Sample Logs and Worksheets. The checklist outlines the procedures and is used to document the results. It can be duplicated as needed." 2. There was no documented evidence that the "Pre-Calibration procedure Checklist" was completed on the date that calibration was performed. 3. The TP#2 listed on CMS from 209 confirmed on 12/16/2021 at 12:32 pm that the laboratory did not follow the OM.
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 surveyor observation of the Quality Control (QC) material, Reagent Packs (RP) and interview with the Testing Personnel (TP), the laboratory retained expired QC and RP for tests perfomed on the BioFire FilmArray Torch analyzer, and Healgen COVID-19 IgG/IgM Rapid Test Cassettes from 10/7/21 to the date of survey. The findings include: 1. COVID-19 IgG/IgM CONTROL Kit Lot # 2101003 used with the Healgen COVID-19 IgG/IgM Rapid Test Cassettes expired 10/7/21. 2. FilmArray Respiratory Panel 2 (RP2) Lot # 228902 used with the BioFire FilmArray Torch analyzer expired 12/1/21 3. The TP#2 listed on CMS from 209 confirmed on 12/16 /2021 at 2:32 pm that the laboratory failed to diascgard expired QC.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration (CAL) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Abbott Cell-Dyn Emerald analyzer from January 2020 to the date of survey. The findings include: 1. A review of Cal records revealed that the laboratory performed Cal once in the calendar year 2021. 2. A review of Cal records revealed that the laboratory did not performed Cal in the calendar year 2020. 3. The TP#2 listed on CMS from 209 confirmed on 12/16/2021 at 10:32 am that the laboratory failed to perform and document Cal once every six months.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document QC on each day of patient testing for tests performed on the BioFire FilmArray Torch analyzer, and Healgen COVID-19 IgG/IgM Rapid Test Cassettes from August 2020 to the date of the survey. The TP#2 listed on CMS from 209 confirmed on 12/16/2021 at 1:32 pm that the laboratory did not perform QC on each day of patient testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test

	results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to take corrective action when one out of two levels of controls were out of range tests performed on the COBAS e411 analyzer from 3/15/21 to the date of survey. The findings include: 1. Control levels were out as follows: a. PreciControl level 1 Lot number 247116 for Folate (FOL) was out of range 3/15/21 and 3/17/21. b. PreciControl level 2 Lot number 247117 for FOL was out of range 3/17/21, 3/19/24, 4/12/21, 4/13/21. c. PreciControl level 1 Lot number 479114 for Antibodies to Thyroid-specific peroxidase (Anti-TPO) was out of range 6/1/21. d. PreciControl level 1 Lot number 451576 for Adrenocorticotropic Hormone (ACTH) was out of range 6/1/21, 6/4/21 and 6/5/21. e. PreciControl level 1 Lot number 479257 for FOL was out of range 6/7/21. f. PreciControl level 2 Lot number 479113 for Anti-TPO was out of range 6/1/21, 7/16/21. g. PreciControl level 2 Lot number 479113 for Anti-TPO was out of range 6/1/21, 7/16/21. h. PreciControl level 1 Lot number 479113 for Anti-TPO was out of range 7/16/21. i. PreciControl level 1 Lot number 411864 for Insulin was out of range 9/24/21, 10/14/21, and 10/15/21 . j. PreciControl level 2 Lot number 411868 for Insulin was out of range 9/24/21 . 2. There was no corrective action documented for the above failures. 3. Approximately 6-10 patient samples were run and reported daily. 4. The TP #2 on CMS form 209 confirmed on 12/17/21 at 1:00 pm that no corrective action was taken for out of range QC.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM) and interview with Testing Personnel (TP) the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems on the date of survey. The finding includes: 1. The OM stated "Controls will be reviewed monthly by the Laboratory Director (LD) or Technical Consultant (TC)" 2. There was no documented evidence that Quality Control (QC) results for Erythrocyte Sedimentation Rate (ESR) were reviewed monthly by the LD or TC. 3. The TP#1 listed on CMS from 209 confirmed on 12/17 /21 at 10:45 am that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. b) Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the procedure to verify new QC material before use from August 2020 to the date of the survey. The Findings include: 1. The laboratory failed to verify controls run on the BioFire FilmArray Torch analyzer, Healgen COVID-19 IgG/IgM Rapid Test Cassettes, and Excyte Mini ERS.

	2. The TP # 2 listed on CMS form 209 confirmed on 12/16/21 at 2:00 pm the laboratory did not follow the procedure to verify new QC lots.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), Manufacturer Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Intervals (RI) used for Erythrocyte Sedimentation Rate (ESR) tests on the date of survey. The findings include: 1. The TP stated the laboratory used the RI listed in the MPI. 2. The MPI RI for ESR 0-15 mm/hr for Male and 0-20 mm/hr for Females. 3. The Female MPI RI was used for both Male and Female ESR test results. 4. The TP#2 listed on CMS from 209 confirmed on 12/16 /2021 at 1:32 pm that the RI on the FR was not that of the RI in the MPI.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 6/12/19 to the date of survey. The findings include: 1. The LD failed to ensure that PS procedures performed on the Sysmex XN-550 analyzer were adequate. Cross refer D6013 4. The LD failed to ensure that the QC program is maintained. Cross refer to D6020. 5. The LD failed to establish a QA plan. Cross refer to D6021.
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 surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to

	ensure that PS procedures performed on the Abbott Cell-Dyn Emerald analyzer were adequate from May 2019 to the date of survey. The finding includes: 1. The LD did not perform precision. 2. The LD did not verify reference intervals/range (normal values) for the laboratory's patient population. 3. The TP #2 listed on CMS from 209 confirmed on 12/16/2021 at 10:20 am that PS records were not adequate.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the QC program is maintained for laboratory services provided from 3/15/21 to the date of the survey. The findings include: 1. Tests run from from 3/15/21 through October 2021 on the COBAS e411 had twenty QC failures that had no documented corrective action. 2. There was no monthly QC available for tests performed on the BioFire FilmArray Torch analyzer, Healgen COVID-19 IgG/IgM Rapid Test Cassettes and Excyte Mini ERS. 3. There was no QC verification for QC material used on the BioFire FilmArray Torch analyzer, Healgen COVID-19 IgG/IgM Rapid Test Cassettes and Excyte Mini ERS. 4. The TP#2 listed on CMS from 209 confirmed on 12/16/2021 the LD did not ensure the QC plan was maintained. .
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Assessment (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the QA program was maintained from 6/12/19 to the date of survey. The finding includes: 1. The QA policy stated as follows: a. A quality assessment review a minimum of 10 test requisitions will be reviewed for completeness of information. b. A quality assessment review a minimum pf 10 specimens will be checked for documentation of proper preparations c. A minimum of 10 specimen will be checked for proper collection when performing a quality assessment review. d. A minimum of 10 patient samples will be checked for proper labeling when performing a quality assessment review. e. A minimum of 10 specimens will be checked for proper processing when performing a quality assessment review. f. A minimum of one day of test logging will be check

	when performing a quality assessment review. 2. There was no documented evidence that the aforementioned QA was performed. 3. The TP #2 listed on CMS form 209 confirmed on 12/17/21 at 10:20 am that the laboratory did not maintain the QA program.