Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1055495	02/01/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on two out of two TP from January 1, 2016 to the date of survey. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. TP #2 did not have a CA in the calendar year 2016. 3. Assessment of problem solving skills was not documented on CA for TP. 4. The Technical Consultant (TC) and Technical Supervisor (TS) did not have a CA for their responsibilities. 5. The TP #2 on CMS form 209 has an Associates Degree and performed the CA on and TC. 6. The TP #2 on CMS form 209 confirmed on 2/1/18 at 1:00 pm that the CA procedure was not performed correctly.
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 coded Chemistry PT results obtained from the American Proficiency Institute (API) for the

	calendar year 2017. The findings include: 1. There was no review or evaluation documented when the laboratory received "Not Graded" results in: a. Chemistry Core 1-2017 - Low Density Lipoprotein (LDL), Triglycerides and Free Thyroxine sample CH-01. b. Chemistry Miscellaneous 2-2017 - Folate sample 1A-06. 2. There was no review or evaluation documented when the laboratory received "Unacceptable" results in: a. Chemistry Core 1-2017 - Aspartate Aminotransferase (AST), Total Bilirubin, Cholesterol, Creatinine, Glucose, LDL and Blood Urea Nitrogen (BUN) - sample CH-04. b. Chemistry Core 1-2017 - Calcium Total samples CH-03 and CH-05. c. Chemistry Core 1-2017 - Carbon Dioxide (CO2) samples CH-01 and CH-05. d. Chemistry Core 1-2017 Magnesium sample CH-05. e. Chemistry Core 1-2017 - Unsaturated Iron Binding Capacity (UIBC) sample CH-01. f. Chemistry Core 3-2017 - Thyroid Stimulating Hormone (TSH) sample CH-11. 3. The TP #2 listed on the CMS form 209 confirmed on 2/1/18 at 1:10 pm that the laboratory did not review all PT results.
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 the procedure for new Quality Control (QC) verification for tests performed on the Cobas Intergra 400 plus and Cobas e411 analyzer from January 2016 to the date of survey. The findings include: 1. The PM stated to "run new QC material as patients to validate the new QC values" but there was no documented evidence of QC being run as patients in 2016 and 2017. 2. The PM stated to run new QC a minimum of three to five times before putting in use but there was no documented evidence that QC was verified. 3. The TP #2 on CMS form 209 confirmed on 2/1/18 at 2:10 pm that the PM was not followed.
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 sureveyor review of Performance Specifications (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify accuracy on Chemistry and Endocrinolgoy tests performed on the Cobas Integra 400 plus and Cobas e411

	analyzer before reporting patient test results from January 1, 2016 to the date of survey. The TP #2 on the CMS form 209 confirmed on 2/1/18 at 1:50 pm that PS were not done.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) and interview with the Testing Personnel (TP), the laboratory did not document corrective action taken when Chemistry and Endocrinology controls were out of range in June 2017. The findings include: 1. There was no documented evidence of Corrective Action (CA) taken when Chemistry and Endocrinology controls were out of range as follows: a. Immunoglobulin E (IgE) Level 1 and 2 - 6/12, 6/13, 6/14, 6/16, 6/20, 6/21 and 6/30. b. Prolactin Level 1 and 2 - 6/1, 6/8, 6/12, 6/13, 6/14, 6/16, 6/20, 6/21, 6/22, 6/28 and 6/30. c. Parathyroid hormone (PTH) Level 1 and 2 - 6/7 and 6/8. d. Sex hormone-binding globulin (SHBG) Level 1 and 2 - 6/1, 6/7, 6/8, 6/12, 6/13, 6/14, 6/16, 6/20 and 6/24. e. Thyroxine (T4) Level 1 and 2 - 6/6. f. Prostate-specific antigen (PSA) Level 1 and 2 - 6/7 and 6/13. g. Thyroid-stimulating hormone (TSH) Level 1 and 2 - 6/1 and 6/6. h. Vitamin D Level 1 and 2 - 6/1 and 6/30. 2. The laboratory ran approximately 75 patients in June 2107. 3. The TP #2 listed on CMS form 209 confirmed on 2/1/18 at 2:00 pm that corrective action was not taken on out of range controls.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) Procedure and interview with the Testing Personnel (TP), the laboratory failed to include monitoring the recording and reporting of results in the CA procedure from January 2016 to the day of the survey. The TP #2 confirmed on 2/1/18 at 1:15 pm that the CA procedure did not include monitoring results.