

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1055495	(X3) Date Survey Completed 06/12/2019
Name of Provider or Supplier Shamra Medical Laboratory, Llc	Street Address, City, State 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Assurance Records (QAR) and interview with the Testing Personnel (TP), the laboratory failed to have a written procedure for Quality Assurance (QA) From 2/1/18 to the date of survey. The TP # 1 listed on CMS form 209 confirmed on 6/12/19 at 11:00 am that the laboratory did not have a written procedure for QA.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Reagent Package Insert (RPI) and interview with the Testing Personnel (TP), the laboratory failed to follow RPI instructions for Folate tests performed on the Roche Cobas e411 analyzer for maintaining specimen integrity from 2/1/18 to the date of survey. The findings include: 1. The RPI for Folate stated "Serum: Stable 2 days at 2-8 degrees Celsius, 4 weeks at -20 degrees Celsius" but the</p>

laboratory did not ensure that Folate specimens were frozen when assayed after 2 days. 2. On 5/20/19 one patient was run and reported four days after collection date. 3. On 6/4/19 three patients were run and reported five days after collection. 4. The TP #1 listed on CMS form 209 confirmed on 6/12/19 at 1:00 pm that RPI instructions were not followed.

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:

a) Based on surveyor review of Manufactures Package Insert, observation of the Quality Control (QC) material, and interview with the Testing Personnel (TP), the laboratory failed to put new expiration dates on PreciControl Varia on the Roche Cobas 400 from February 2018 to the date of survey. The findings include. 1. The MPI for PreciControl Varia stated that QC material for routine chemistry tests expires 72 hours after reconstitution if stored at 2 to 8 degrees Celsius. 2. The TP stated the controls are kept for 21 days stored at 2 to 8 degrees Celsius. 3. The TP was not aware that QC material expired 72 hours after reconstitution. 4. Approximately 150 patients run and reported for routine chemistry. 5. The TP #1 on CMS form 209 confirmed on 6/12/19 /19 at 11:00 am the laboratory failed to put new expiration dates on the control material. b) Based on surveyor review of Manufactures Package Insert, observation of the Quality Control (QC) material, and interview with the Testing Personnel (TP), the laboratory failed to put new expiration dates on PreciControl Tumor Marker Controls on the Roche Cobas e411 from February 2018 to the date of survey. The findings include. 1. The MPI for PreciControl Tumor Marker controls stated that QC material for Ferritine and Prostate-Specific antigen (PSA) tests expires 14 days after reconstitution if stored at 2 to 8 degrees Celsius. 2. The TP stated the controls are kept for 21 days stored at 2 to 8 degrees Celsius. 3. The TP was not aware that QC material expired 14 days after reconstitution. 4. Approximately 100 patients run and reported. 5. The TP #1 on CMS form 209 confirmed on 6/12/19 /19 at 11:00 am the laboratory failed to put new expiration dates on the control material.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on lack of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least once every six months for Routine Chemistry and Endocrinology tests performed on the Roche Cobas 400 and e411 analyzer from February 2018 to the date of the surveyor. The TP #1 listed on CMS for 209 confirmed on 6/12/19 at 12:00 pm CV was not performed every six months.