

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D1048389	<b>(X3) Date Survey Completed</b> 01/11/2018
<b>Name of Provider or Supplier</b> Excell Clinical Laboratory	<b>Street Address, City, State</b> 95 Dermody Street, Cranford, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a) Based on surveyor review of the Competency Assessment (CA) records and interview with the General Supervisor (GS), the laboratory failed to perform CA correctly on one out of three GS in 2017. The finding includes: 1. The laboratory did not document how GS was assessed. 2. The GS # 2 listed on the CMS form confirmed on 1/10/18 at 11:00 am that CA was not performed correctly on GS. b) Based on surveyor review of CA and interview with the GS, the laboratory did not perform CA on two of two Testing Personnel (TP) correctly in 2016 and 2017. The finding includes: 1. TP were not evaluated with six elements on each specialty performed. 2 The GS # 2 listed on the CMS form confirmed on 1/10/18 at 11:00 am that CA performed correctly.</p>
<b>D5309</b>	<p><b>TEST REQUEST</b> CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on review of Test Requisition (TR), Laboratory Information System (LIS) and interview with the General Supervisor (GS), the laboratory failed to ensure that</p>

information from TR was transcribed accurately into the LIS in November 2017. The findings include: 1. Review of two out of eight TR from November 2017 revealed that there were transcription errors. 2. Accession # 00417151 TR had incorrect address (name of the city) and # 00417073 had time of collection incorrect. 3. Both TR were checked and signed by the reviewer. 4. The GS # 2 listed on the CMS form 209 confirmed on 1/10/18 at 12:15 pm that the laboratory did not ensure information was transcribed accurately.

**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:

a) Based on surveyor review of Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to follow G-SOP-81 procedure from 9/10/15 to the date of survey. The finding includes: 1. The G-SOP-81 stated Performance Appraisal will be evaluated annually but there was documentation that it was done. 2. The GS # 2 listed on the CMS form 209 confirmed on 1/10/18 at 11:00 am that the procedure was not followed. b) Based on surveyor review of PM and interview with the GS, the laboratory failed to include Manual test result entry verification procedure in G-SOP-20b from 9/10/15 to the date of survey. The GS # 2 listed on the CMS form 209 confirmed on 1/10/18 at 11:00 am that the procedure was 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:

a) Based on surveyor review of the Package Insert (PI), observation of rotator and interview with the General Supervisor (GS), the laboratory failed to follow Syphilis test procedure from 9/10/15 to the date of survey. The finding includes: 1. The laboratory did not use humidifier cover as stated in the PI of the test. 2. The GS # 2 listed on the CMS form 209 confirmed on 1/11/18 at 10:30 am that syphilis test procedure was not followed. 35471 b) Based on surveyor review of the Manufacturers Package Insert (MPI), Final Reports (FR) and interview with the Laboratory Director (LD), the laboratory failed to follow the MPI for Immunology tests performed on the Dynex DS2 from 9/10/15 to the date of the survey. The finding includes: 1. A review of the FR revealed test results and the interpretation for Measles, Mumps and Rubella included an immune status but the interpretation on the MPI did not indicate an immune status. 2. The LD confirmed on 1/11/18 at 1:10 pm the laboratory did not follow the MPI.

<p><b>D5449</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the manufacturer package insert and interview with the General Supervisor (GS), the laboratory failed to perform and document a positive and negative control for Mononucleosis and Helicobacter Pylori tests on each day of patient testing from January 2016 to the date of the survey. The GS # 2 listed on the CMS form 209 confirmed on 1/11/18 at 12:00 pm that the laboratory did not perform and document quality control on each day of patient testing.</p>
<p><b>D5805</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of the Final Report (FR) and interview with the General Supervisor (GS), the labortaory failed to report Urinalysis results correctly from 9/10 /15 to the date of survey. The finding includes: 1. Tha laboratory reported units of measurements for qualitative Urinalysis results. 2. The GS # 2 listed on the CMS form 209 confirmed on 1/11/18 at 11:00 am that urinalysis results were not reported correctly. 35471 b) Based on surveyor review of the Immunology Final Report (FR) and interview with the Laboratory Director (LD), the laboratory reported unit of measurements for qualitative Zeus Eliza Tests performed on the Dynex DS2 from September 2015 to the date of survey. The LD confirmed on 1/11/18 at 1:15 pm that qualitative tests were reported with unit of measurements.</p>
<p><b>D5807</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Final Report and interview with the General Supervisor</p>

(GS), the laboratory failed to report urine microscopic reference ranges accurately from 9/10/15 to the date of survey. The finding includes: 1. The laboratory reported numerical values such as 0-10 and None Seen reference range for Epithelial cell, White Blood cell, Bacteria, Red Blood cell and Casts. 2. The GS # 2 listed on CMS form 209 confirmed on 1/11/18 at 11:30 AM that reference ranges were incorrect.