

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0146454	<b>(X3) Date Survey Completed</b>  06/10/2021
<b>Name of Provider or Supplier</b>  Olitsa Roth Md	<b>Street Address, City, State</b>  5211 15th Avenue, Brooklyn, NY	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of Quality Control (QC) records, calibration records for the QBC Autoreader hematology analyzer and QC records for the Select Strep Agar (SSA) media and an interview with the laboratory testing person, the laboratory failed to retain copies of the control &amp; calibration records, control &amp; calibration assay information sheets for the QBC Autoreader analyzer and National Committee for Clinical Laboratory Standards (NCCLS) SSA media assay sheets from January 1, 2019 through December 25, 2020. FINDINGS: 1. The laboratory testing person confirmed on June 10, 2021 at approximately 2:30 PM, the laboratory failed to retain copies of the control &amp; calibration records, control &amp; calibration assay information sheets for the QBC Autoreader analyzer and NCCLS SSA media assay sheets from January 1, 2019 through December 25, 2020. 2. The laboratory QBC Autoreader laboratory failed to retain copies of control &amp; calibration records, control &amp; calibration assay information sheets from January 1, 2019 through December 25, 2020. 3. The manufacturer for the hematology QBC Autoreader requires the calibration rod is used to verify the optic &amp; electronic checks prior to performing 2 levels (low/high) controls, each day of testing. a. testing person stated, " that she could not locate the file box for the control, calibration QC results and the assay sheets." b. surveyor could not determine the number of control lots the laboratory used for performing quality control for the QBC Autoreader during this time. 4. The laboratory did retain copies for the current lots used for QBC Autoreader controls Low/High Q584 expiration date 5/20/21 Q585 expiration date 5/23/2021 Q586 expiration date 6 /13/2021 5. The laboratory did not retain the NCCLS labels for the SSA media for the</p>

following lots #8926334 expiration date 3/3/2019 #9052211 expiration date 6/2/2019 9371153 expiration date 8/30/2019 #9576542 expiration date 11/07/2019 #9795534 expiration date 11/15/2020 #012674 expiration date 3/20/2020 #016222 expiration date 9/18/2020 #018987 expiration date 11/20/2020 #106441 expiration date 2/05/2021

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) records for calendar years 2019, 2020 and 1st event of 2021 and confirmed in an interview with the laboratory testing person, the laboratory failed to retain documentation to include signed attestation forms hematology and bacteriology challenges for the 2019, 2020 and 2021 events.

**D5471**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the sub-specialty Bacteriology/throat culture QC records for 2019, 2020 and 2021, the QC procedures for the 0.04 bacitracin disc and an interview with the laboratory testing person, the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin disc for positive and negative reactivity from January 7, 2019 through December 25, 2020. FINDINGS: 1. The laboratory testing person confirmed on June 10, 2021 at approximately 2:30 PM, that the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin discs for positive and negative reactivity. a. the laboratory did not perform QC for the following lot numbers and did not record the expiration dates for these lots: 2019 - #9152234/#9416772/#9628813/#9871114/#998437 2020- #0037412 /#0056413/#0072123/#0085512/#0092123 2021- #0122352/#0125486 2.

Approximately 500 patient specimens were tested and reported for Bacteriology /throat culture during the above time.