

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0928007	(X3) Date Survey Completed 01/13/2022
Name of Provider or Supplier Optum Medical Care Pc	Street Address, City, State 2800 Marcus Avenue, Suite 103, Lake Success, NY	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: On January 13, 2022 about 11 am, based on review of the histology laboratory's procedure manual and interview with the laboratory administrative director, the laboratory failed to follow embedding process procedure named "Securing blocks between embedding and microtomy." refer D6021 Finding: 1. The procedure named "Securing blocks between embedding and microtomy" states "Embedder will document date, time and number of blocks being placed into bin and initial on the 'Daily Block Counting Log.' Histotech will document date, time and number of blocks being removed from bin and initial on the 'Daily Block Counting Log.'" 2. Starting the</p>

date 5/2/2021-1/13/2022, the Daily Block Counting Log was incomplete. The laboratory did not document time of number of blocks placed in bin, number of blocks placed inside the bin, initials, and time of number of blocks removed.

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's review of the laboratory's QA policies/procedures and an interview with the administrative director, the laboratory failed to ensure a written QA policy was established and maintained for the caldenar years 2021 up unto January 2022. Refer to: D5403