

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0202381	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Gary V Gordon Md	Street Address, City, State Lankenau Medical Building Suite 137, Wynnewood, PA	
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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Based on review of laboratory procedure manuals and interview with the laboratory director (LD), the laboratory failed to establish a complete competency assessment procedure to assess the competency on 2 of 3 testing personnel (TP) performing synovial fluid examinations from 11/21/2017 to the date of survey. Findings include: 1. On the day of survey, 12/17/2019, the laboratory could not provide a complete competency assessment procedure to assess the competency on 2 of 2 TP performing synovial fluid examinations in 2018 and 2019. 2. The LD confirmed the findings above on 12/17/2019 around 09:45 am.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedures and interview with the laboratory director (LD), the laboratory failed to include, quality control (QC) procedures and reference intervals/ result interpretations in the synovial fluid examination procedure manual from 2017 to the date of survey. Findings Include: 1. On the day of survey, 12/17/2019, review of the laboratory's procedure manual revealed, the synovial fluid examination procedure did not include the following from 11/21/2017 to 12/17/2019. - QC procedures. - Reference intervals/ result interpretations. 2. The LD confirmed the findings above on 12/17/2019 around 9:50 am.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

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.

This STANDARD is not met as evidenced by:

Based on review of synovial fluid examination logs, and interview with the laboratory director (LD), the laboratory failed to document quality control (QC) procedures on 183 of 183 synovial fluid examinations from 2017 to the date of survey. Findings Include: 1. On the day of survey, 03/28/2019, review of synovial fluid examination logs revealed, the laboratory did not document QC performed each day of patient testing on 183 of 183 synovial fluid examinations from 11/21/2017 to 12/17/2019. 2. In 2017 (11/21/2017 to 12/31/2017) , 6 synovial fluid examination were analyzed. 3. In 2018, 102 synovial fluid examination were analyzed. 4. In 2019 (01/01/2019 to 12/17/2019), 75 synovial fluid examination were analyzed. 5. The LD confirmed on 12/19/2019 around 9:50 am. ** Repeat Deficiency for the past 2 inspections.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manuals and interview with the laboratory director (LD), the laboratory director failed to ensure quality assessment

(QA) programs were established and maintained to assure the quality of the laboratory's services from November 2017 to November 2019 (25 out of 25 months). Findings Include: 1. On the day of survey, 12/17/2019, review of the laboratory's manuals revealed, the laboratory did not establish QA procedure to assess the laboratory's systems from November 2017 to November 2019 (25 out of 25 months). 2. The LD confirmed on 12/17/2019 around 9:55 am, the laboratory does not a have QA procedure, nor were QA activities documented on a periodic bases.