

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0681074	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Adam S Plotkin Md Pa D/B/A	Street Address, City, State 5210 Linton Blvd Ste 307, Delray Beach, FL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not verify the accuracy of Mohs surgery slides twice annually. Findings include: Review of Mohs surgery proficiency testing records for the past two years on 09/20 /18 revealed that there was no documentation to indicate that proficiency testing had been performed in 2017. The laboratory consultant confirmed at 11:25 a.m. on 09/20 /18 that proficiency testing for 2017 could not be located.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, there was no documentation of control procedures having been performed on each new batch of media used for mycology cultures. Findings include: Review of mycology records om</p>

	<p>09/20/18 revealed that there was no documentation of quality control organisms being used to check each batch of media for its ability support growth and produce the correct biochemical response. The laboratory consultant confirmed that documentation had not been located at 12:19 p.m. on 09/20/18.</p>
<p>D6045</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, there was no documentation to indicate that the Mohs technologist had received training for the testing that she performed. Findings include: Review of personnel records on 09/20/18 revealed that there was no training documentation for the Mohs technologist that started testing in July, 2017. The laboratory consultant confirmed at 11:25 a.m. on 09/20/18 that the only documentation was the competency that was performed in September, 2018.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with laboratory personnel, the technical consultant did not ensure that the Mohs technologist had been evaluated semiannually during her first year. Findings include: Review of personnel records on 09/20/18 revealed that the technologist that started employment there on 07/24/17 did not have a competency evaluation until 09/18. The laboratory consultant confirmed at 11:25 a.m. on 09/20/18 that the technologist started working there in July of 2017 and the only competency that was performed was in September of 2018.</p>