

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0924065	<b>(X3) Date Survey Completed</b> 07/28/2021
<b>Name of Provider or Supplier</b> David B Minor, Md, Pc	<b>Street Address, City, State</b> 1516 South Yorktown Place, Tulsa, OK	
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>D0000</b>	The recertification survey was performed on 07/28/2021. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the technical consultant at the conclusion of the survey.
<b>D5217</b>	<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 a review of records and interview with the technical consultant, the laboratory failed to verify the accuracy of Fungal Culture, KOH, and Scabies testing at least twice annually. Findings include: (1) On 07/28/2021 at 09:30 am, the technical consultant stated to the surveyors the following testing was performed in the laboratory: (a) Fungal culture testing (positive/negative growth) using Acu-Mycosel media; (b) KOH (Potassium Hydroxide) testing as a PPM (Provider Performed Microscopy) procedure; (c) Scabies testing as a PPM procedure. (2) Surveyor #1 reviewed 2019, 2020, and to date in 2021 and identified the testing had not been verified for accuracy twice annually as follows: (a) Fungal Culture testing had not been verified for accuracy between 11/10/2019 and 06/24/2021; (b) KOH testing had not been verified for accuracy between 11/10/2019 and 06/24/2021; (c) Scabies testing had not been verified for accuracy prior to 06/24/2021. (3) The records were reviewed with the technical consultant who stated to surveyor #1 on 07/28/2021 at 10:35, the testing had not been verified for accuracy at least twice annually as shown above. NOTE: D5217 was cited on the recertification surveys performed on 08/02/2019.</p>
<b>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p>

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory supervisor, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: (1) On 07/28/2021 at 09:30 am, the technical consultant stated the following to the surveyors: (a) Fungal culture testing (positive/negative growth) was performed using Acu-Mycosel media; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 11/05/2018). The section titled, "Quality Assessment: Ongoing Monitoring for QCP Effectiveness" required an annual review of the QCP (Quality Control Plan); (3) Surveyor #1 reviewed records for 2019, 2020, and to date in 2021 and could not locate annual QA reviews since the IQCP had been approved on 11/05/2018; (4) The surveyor reviewed the records with the technical consultant and asked if there was documentation of QA reviews to evaluate the QCP annually. The technical consultant stated to surveyor #1 on 07/28/2021 at 10:10 am the QA reviews had not been performed annually as stated in the policy.