

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0924065	(X3) Date Survey Completed 08/02/2019
Name of Provider or Supplier David B Minor, Md, Pc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	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.
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 a review of records and interview with the technical consultant, the laboratory failed to verify the accuracy of KOH testing at least twice annually. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyors KOH (Potassium Hydroxide) testing was performed as a PPM (Provider Performed Microscopy) procedure; (2) Surveyor #2 reviewed 2018 and 2019 records and identified the testing had not been verified for accuracy twice annually during 2018. Although the testing had been verified for accuracy towards the end of 2018 (11/6,21,28/18 and 12/05/18), there were no records the testing had been verified for accuracy earlier in the year; (3) The records were reviewed with the technical consultant who stated he did not begin employment at the facility until November 2018 and KOH testing had not been verified for accuracy prior to November 2018.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p>

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for performing fungal culture testing. Findings include: (1) At the beginning of the survey, the technical consultant stated the following to the surveyors: (a) Fungal culture testing (positive/negative growth) was performed using Acu-Mycosel media; (b) Cultures were incubated at room temperature (68-86 degrees F-Fahrenheit). (2) The surveyors reviewed the manufacturer's package insert for the Acu-Mycosel media. Under the heading "Procedure" it stated, "Examine the cultures after 24 hours and repeat daily. Culture tubes should be held for 4 weeks before being considered negative"; (3) The surveyors requested patient test records from 01/01/19 through the day of the survey. The technical consultant provided the surveyors with the patient "Fungal Culture Reading Logs"; (4) The surveyors reviewed 28 patient fungal culture records performed during the requested timeframe. The review verified the laboratory did not follow the manufacturer's instructions. The documentation verified the cultures were being examined on a weekly basis instead of being examined after 24 hours and repeated daily until the final result was reported for 28 of 28 patient records reviewed: (a) Record #1 - Inoculated on 01/02/19 (b) Record #2 - Inoculated on 01/08/19 (c) Record #3 - Inoculated on 01/09/19 (d) Record #4 - Inoculated on 01/10/19 (e) Record #5 - Inoculated on 01/10/19 (f) Record #6 - Inoculated on 01/22/19 (g) Record #7 - Inoculated on 01/25/19 (h) Record #8 - Inoculated on 01/30/19 (i) Record #9 - Inoculated on 01/29/19 (j) Record #10 - Inoculated on 02/05/19 (k) Record #11 - Inoculated on 02/15/19 (l) Record #12 - Inoculated on 02/27/19 (m) Record #13 - Inoculated on 03/12/19 (n) Record #14 - Inoculated on 03/13/19 (o) Record #15 - Inoculated on 03/19/19 (p) Record #16 - Inoculated on 03/20/19 (q) Record #17 - Inoculated on 03/28/19 (r) Record #18 - Inoculated on 04/04/19 (s) Record #19 - Inoculated on 04/12/19 (t) Record #20 - Inoculated on 05/06/19 (u) Record #21 - Inoculated on 05/08/19 (v) Record #22 - Inoculated on 05/17/19 (w) Record #23 - Inoculated on 05/20/19 (x) Record #24 - Inoculated on 05/28/19 (y) Record #25 - Inoculated on 06/06/19 (z) Record #26 - Inoculated on 06/07/19 (aa) Record #27 - Inoculated on 06/11/19 (bb) Record #28 - Inoculated on 06/11/19 (5) The surveyors reviewed the records with the technical consultant who stated the cultures, as indicated above, had been examined on a weekly basis and not examined after 24 hours and repeated daily until the final result was reported.