

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2264828	<b>(X3) Date Survey Completed</b>  12/05/2023
<b>Name of Provider or Supplier</b>  John G Deleonibus Dpm Pa	<b>Street Address, City, State</b>  2086 Generals Hwy #101, Annapolis, MD	
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>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: Based on review of instrument data, review of the procedure, and interview with the testing person (TP), the laboratory failed to ensure that the correct organisms were listed in the instrument for accurate transcription into the final report. Findings: 1. The laboratory performed a fungal panel molecular assay that tested for 21 gene targets. 2. For patient results, the TP reviewed the cycle threshold (Ct) values for each of the 21 gene targets from the instrument data, determined if the Ct value was above or below the defined cutoff value for that gene target, then manually transcribed which gene targets were "detected" onto the final report template. 3. Each gene target was labeled in the instrument based on which well the reagents for that target were located. 4. According to the procedure, well G3 contained reagents to detect Malassezia species, Trichophyton anthropophilic species, and Trichophyton zoophilic species. 5. The instrument showed that well G3 contained Meyerozyma guilliermondii, Microsporum canis, and Sarocladium strictum. 6. As a result, any patient that showed positive amplification in well G3 would have had the incorrect organism listed as "detected" on the final report. 7. During the onsite revisit survey on 12/01/2023 at 2:00 PM, the TP confirmed that the incorrect organisms were listed in well G3 on the instrument.</p>

## TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(2)

Each individual performing high complexity testing must maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens.

This STANDARD is not met as evidenced by:

Based on review of split sample testing results and interview with the outside laboratory consultant (OLC), the laboratory failed to evaluate proficiency testing (PT) samples in the same manner as patient specimens. Findings: 1. The laboratory performed a wound panel molecular assay that detected 38 gene targets and was enrolled with American Proficiency Institute (API) for PT. 2. The laboratory performed alternate split sample PT for the gene targets that were not included in API PT program. 3. There was no procedure that described how the alternate split sample PT samples were to be handled, tested, reported, and evaluated. 4. Review of the 112023 molecular wound split sample testing event showed that the samples were not reported and evaluated in the same manner as patient specimens. 5. Patient results are reported as either "detected" if the patient's cycle threshold (Ct) value is equal to or less than the defined Ct cutoff value or "not detected" if the patient's Ct value is greater than the defined Ct cutoff value. 6. All split sample results were reported as a Ct value not "detected" or "not detected" as patient results were reported. 7. The OLC stated that the Ct cutoff value for the comparing laboratory (Lab B) was 38 so that any result that was less than or equal to 38 would be "detected" and any result that was greater than 38 would be "not detected." All Lab B results listed on the 112023 molecular split sample testing event would have been reported as "detected." 8. The laboratory's Ct cutoff for *Staphylococcus saprophyticus* was 33.13. The laboratory's result for sample ASL-07132210219 was 34.33 and would have been reported as "not detected." The result was called a match. 9. The laboratory's Ct cutoff for *Staphylococcus aureus* was 32.08. The laboratory's results for sample ASL-07132210219 was 32.10 and would have been reported as "not detected." The result was called a match. 10. The laboratory's Ct cutoff for *mecA* was 33.56. The laboratory's results for sample S-12072210082 was 35.99 and would have been reported as "not detected." The result was called a match. 11. The laboratory's Ct cutoff for *Enterococcus* species was 32.42. The laboratory's results for sample S-03022310009 was 36.33 and would have been reported as "not detected." The result was called a match. 12. The report for the 112023 molecular wound split sample testing event did not define acceptability criteria or how the results were to be evaluated and compared. 13. During a phone conversation on 12/01/2023 at 2:00 PM, the OLC confirmed that results from the alternate split sample PT events were not evaluated the same as patient results and there was no procedure defining how to process, report, and evaluate the alternate split sample PT results.