

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2243031	<b>(X3) Date Survey Completed</b> 11/29/2023
<b>Name of Provider or Supplier</b> Superb Diagnostic Llc	<b>Street Address, City, State</b> 810 Main Street, Hackensack, NJ	
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>D2003</b>	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to establish and maintain the accuracy of Microbiology tests from 11/16/21 to the date of survey. This findings include. 1. The PT provider used by the laboratory American Proficiency Institute (API) did not include all analytes run on the Gastrointestinal (GI) panel performed by the laboratory a) 3rd event 2023 did not include Enterichio coli, Shiga-like Toxin producing E. coli. b) 2nd event 2023 did not include Enterichio coli, Shiga-like Toxin producing E. coli, 2. The PT provider used by the laboratory API did not include all analytes run on the Respiratory Panel (RP) panel performed by the laboratory a) 3rd 2023 event did not include Enterovirus b) 2nd 2023 event did not include Enterovirus 2. The PT provider used by the laboratory API did not include all analytes run on the Nail Panel (NP) panel performed by the laboratory. a) 3rd event 2023 did not include Curvularia lunta, Klebsiella ocytoca, Klebsielle pneumonia. b) 2nd event 2023 did not include Curvularia lunta, Klebsiella ocytoca, Klebsielle pneumonia. 3. The PT provider used by the laboratory API did not include all analytes run on the Wound Panel (WP) panel performed by the laboratory a) 3rd 2023 event did not include B. atrophaeus, Citrobacter species, Enterobacter species, Enterococcus species, Klebsiella pneumonia, Staphylococcus, coagulase negative, VIM, NDM, ermA/B/C, qnrA, tetM, OXA. 4. The LD confirmed on 11/29/23 at 12:45 pm not all analytes for the above mentioned panels were performed.</p>
<b>D5417</b>	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observation of laboratory reagents for the Luminex Aries analyzer, and interview with the Testing Personnel (TP), the laboratory failed to discard expired reagents for the Luminex Aries analyzer from 11/3/23 to the date of survey. The findings include: 1. Two boxes of Luminex Aries Stool Resuspension kits lot # 339314 expired on 11/3/23. 2. TP #1 as listed on the CMS-209 form confirmed on 11/29/23 at 12:00 pm that the laboratory failed to discard expired reagents for the Luminex Aries analyzer.

**D5481**

**CONTROL PROCEDURES**

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

A) Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) and interview with the Testing Personnel (TP), the laboratory failed to have accurate data that demonstrates the stability of the test system and supports the Quality Control (QC) type and frequency to support their Risk Assessment (RA) for Bacteriology and Virology testing on the Luminex Aries System before reporting patient results from 5/31/23 to the date of the survey. The findings include: 1. The "Historical Quality Review" section of the IQCP for QC of the Aries System states, "This laboratory has been using the Aries molecular test to detect Pathogen, C. difficile, MRSA, Flu A/B/RSV, Group A Strep from 04/2023- 05/2023 for 31 days straight without any significant QC problems. No issues related to QC performance have been identified." 2. The following reports had failed QC runs during the 31 day RA testing for the Luminex Aries System: a. Sample Identification (ID) "Zepto HSV POS" control failed on Day 6 for the Aries Herpes Simplex Virus (HSV) 1&2 Herpes Simplex (HS) A assay. b. Sample ID "Zepto CDIFF NEG" control failed on Day 8 for the Aries C. difficile CD A assay. c. Sample ID "Zepto HSV POS" control failed on Day 11 for the Aries HSV 1&2 HS A assay. d. Sample ID "Zepto HSV POS" control failed on Day 17 for the Aries HSV 1&2 HS A assay. e. Sample ID "Zepto HSV NEG" control failed on Day 18 for the Aries HSV 1&2 HS A assay. f. Sample ID "Zepto FLU NEG" control failed on Day 24 for the Aries Flu A/B & Respiratory Syncytial Virus (RSV) FP A assay. g. Sample ID "Zepto HSV POS" control failed on Day 25 for the Aries HSV 1&2 HS A assay. h. Sample ID "Zepto FLU POS" control failed on Day 31 for the Aries Flu A/B & RSV FP A assay. 3. There was no documented evidence the aforementioned failed QC runs were evaluated in the IQCP RA for the Luminex Aries System. 4. TP #1 as listed on the CMS-209 form confirmed on 11/29/23 the Luminex Aries System had QC failures during the 31 days of testing. B) Based on surveyor review of the laboratory's IQCP and interview with the TP, the laboratory failed to have a complete RA in the IQCP for Bacteriology and Virology testing on the Luminex Aries System before reporting patient results from 5/31/23 to

the date of the survey. The findings include: 1. The "Summary of in-house data from QC testing" stated "Review of QC records for the past 12 months (XX to XX dates) that contained approximately XX results demonstrated % occurrence of random QC errors that corrected upon repeat testing." 2. The "Summary of in-house data from routine instrument performance checks stated " Review of instrument QC records for the past 12 months (XX to XX dates) that contained approximately XX routine checks of instrument XYZ and 1 report following scheduled maintenance performed by the company's service engineer revealed no instrument performance problems that would impact patient results." 3. The laboratory failed to include all pertinent information needed to complete the aforementioned sections of the RA. 4. TP #1 confirmed on 11/29/23 at 1:30 pm the RA was incomplete for the Luminex Aries System.