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| <p><b>Statement of Deficiencies</b></p>   | <p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>45D2209518</p>                    | <p><b>(X3) Date Survey Completed</b></p> <p>03/26/2024</p> |
| <p><b>Name of Provider or Supplier</b></p> <p>Bioexcel Diagnostics, Llc</p>   | <p><b>Street Address, City, State</b></p> <p>2636 South Loop Freeway West Suite 110, Houston, TX</p> |  |
| <p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p> |  |  |

| <p><b>(X4) ID Prefix Tag</b></p> | <p><b>Summary Statement of Deficiencies</b></p>   |
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| <p><b>D0000</b></p>              | <p>Based on an announced validation inspection on 3/26/2024, the laboratory was found to be in compliance with the CLIA regulations found at 42 CFR 493.1 through 493.1780. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference.</p>   |
| <p><b>D5311</b></p>              | <p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b><br/>CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of laboratory records, random review of patient results from 2023 to 2024, and confirmed in interview, the laboratory failed to document preanalytical studies to substantiate the preanalytical claims per the laboratory policy for two of two test panels (wound and fungal) reviewed on the Thermofisher TaqMan assay/PCR/Takara. A. wound panel B. Fungal panel Findings included: A. wound panel 1. Review of laboratory records available revealed the laboratory performed molecular testing of wound specimens for the following 33 organisms and 39 antibiotic resistant genes: Panel: Wound Infection Molecular Insight - Organisms<br/>Acinetobacterbaumannii Actinotinum schaalii Aerococcus urinae, Bacteroides fraiis, Candida albicans, Candida aurs, Candida glabrata, Candida parapsilsis Citkin deterfreundii, Citrobaacter koseri, Coagulase Negative Staph, Corynebacterium regeli, Enterobater cloacae, Enterococcus facalis, Enterococcus faecium, Escherichia col; Kinella Kingae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsilla pneumoniae,</p> |

Morganella morganii, Mycoplasma hominis, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pyogenes, Ureaplasma urealyticum, Viridans Group Panel: Wound Infection Molecular Insight - Resistance Genes AAC (6)-Ib (aac(6)-Ib), Ant(3),APH(3)-VIb (aph (3)-VI, AAC (6)-Ib-cr (aac(6)-Ib-cr), ACC, BIL/LAT/CMY, CTX-M group 1, CTX-M group 2, CTX-M group 9, CTX-M group 8/25, DHA, Erm (A)/Erm (B), FOX, IMP-1 group, IMP-16, IMP-7, KPC, MOX/CMY, Mef(A), OXA-1, GES, OXA-23, OXA-72, OXA-40, blaOXA-48, PER-1, PER-2, QnrA, QnrS, Qnr B, SHV, Sull, Sul2, Tet(M), VEB, VIM, Van Group, ampC, dfrA5, dfrA1, mecA 2. Review of the laboratory policy BDX Wound Collection, Handling, and Transport (SOP021) under Specimen Viability it stated "Swab specimens for bacterial investigations collected using ESwab should be transported directly to the laboratory, preferably within 2 hours of collection to maintain optimum organism viability. If immediate delivery or processing is delayed, then specimens should be at 2C - 25C and processed within 144 hours." 3. Review of the wound preanalytical studies performed did not include 29 of the 33 organisms and 39 of 39 antibiotic resistant genes. Panel: Wound Infection Molecular Insight - Organisms Acinetobacterbaumannii Actinotignum schaalii Aerococcus urinae, Bacteroides fraiis, Candida albicans, Candida auris, Candida parapsilosis Citrinia deterefrundii, Citrobacter koseri, Corynebacterium regeli, Enterococcus faecalis, Enterococcus faecium, Escherichia coli; Kinella Kingae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Mycoplasma hominis, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pyogenes, Ureaplasma urealyticum, Viridans Group Panel: Wound Infection Molecular Insight - Resistance Genes AAC (6)-Ib (aac(6)-Ib), Ant(3),APH(3)-VIb (aph (3)-VI, AAC (6)-Ib-cr (aac(6)-Ib-cr), ACC, BIL/LAT/CMY, CTX-M group 1, CTX-M group 2, CTX-M group 9, CTX-M group 8/25, DHA, Erm (A)/Erm (B), FOX, IMP-1 group, IMP-16, IMP-7, KPC, MOX/CMY, Mef (A), OXA-1, GES, OXA-23, OXA-72, OXA-40, blaOXA-48, PER-1, PER-2, QnrA, QnrS, Qnr B, SHV, Sull, Sul2, Tet(M), VEB, VIM, Van Group, ampC, dfrA5, dfrA1, mecA 4. Further review of the wound stability studies revealed specimens were stored and analyzed at 2-8 C, 15-25 C, freezer -25 C, and incubator at 37C. No documentation of a stability studies at 9-14 C were available for review. 5. Random review of the specimen receipt log from 2023 and 2024 revealed wound specimens were received at temperatures ranging from 9-14 C for the following five days. 01/30/2024 13.3 C 12/04/2023 8.7 C 11/28/2023 13.6 C 11/24/2023 11.2 C 10/25/2023 8.3 C 6. Review of patient test results from the above dates confirmed the laboratory received and analyzed wound specimens for the following five patients. 01/30/2024 SP24-003833Wwnd Results: Detected Coagulase Negative Staph, Staphylococcus aureus, Tetracycline, Macrolide, Methicillin 12/04/2023 SP23-045022Wwnd Results: Detected Staphylococcus aureus 11/28/2023 SP23-0044249Wwnd Results: None detected 11/24/2023 SP23-00440044Wwnd Results: Detected Coagulase Negative Staph, Pseudomonas aeruginosa 10/25/2023 SP23-039457Wwnd Results: Detected Coagulase Negative Staph, Enterococcus faecalis, Staphylococcus aureus, macrolide/clindamycin, methicillin, tetracycline 7. In an interview with the laboratory director on 03/26/2024 at 1140 hours in the office, he confirmed the above findings. He acknowledged that the studies should include all target organisms and genes and at all temperatures received. B. fungal panel 1. Review of laboratory records available revealed the laboratory performed molecular testing on nail clippings for the following 18 organisms: Candida albicans, Candida auris, Candida dubliniensis, Candida glabrata, Candida krusei, Candida lusitanae, Candida parapsilosis, Candida tropicalis, Epidermophyton floccosum, Fusarium solani, Microsporium group, Trichophyton interdigitale, Trichophyton rubrum, Acremonium strictum, Alternaria,

Aspergillus niger, Aspergillus terreus, Neofusicoccum mangiferae 2. Review of the laboratory policy BDX Fungal Collection, Handling, and Transport (SOP 042) under stability, it stated "The sample [nail clipping] is stable for 60 days at room temperature, due to clinical necessities of the sample, transfer to lab within 24 hours." 3. Review of the fungal stability studies performed did not include 7 of 18 organisms. Studies were also performed at room temperature. No studies at refrigerated or ambient temperature (2-14 C) were available for review. Candida albicans, Candida auris, Acremonium strictum, Alternaria, Aspergillus niger, Aspergillus terreus, Neofusicoccum mangiferae 4. Random review of the specimen receipt log from 2023 to 2024 revealed nail clippings specimens were received at refrigerated and ambient temperatures on the following four days. 01/25/2024 7.5 C 11/22/2023 4.7 C 10/25/2023 8.3 C 10/24/2023 8.3 C 5. Review of the patient test results for the above dates confirmed the laboratory received and analyzed the nail clippings for the following four patients. 01/25/2024 SP24-002943N Results: Detected Fusarium solani 11/22/2023 SP23-043701N Results: No organisms detected 10/25/2023 SP23-039299N Results: Detected Trichophyton rubrum 10/24/2023 SP23-039226N Results: Detected Trichophyton interdigitale 6. In an interview with the laboratory director on 03/26/2024 at 1300 hours in the office, he confirmed the above findings.