

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0317977	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Mississippi Urology Clinic Plc	Street Address, City, State 501 Marshall Street Suite 301, Jackson, MS	
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
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for the MicroScan Walkaway 40 Plus microbial identification/susceptibility system since the last survey on 3/18/2021 and manufacturer's instructions for Beckman Coulter MicroScan Dried Gram Positive and Dried Gram Negative panels, the laboratory failed to document positive and negative reactivity for each of the biochemical reagents for three new lots of Positive Combo (PC) 33 panels and three new lots of Negative Urine Combo (NUC) 73 panels put in use since 3/18/2021. Findings include: Review of QC records for the MicroScan Walkaway 40 Plus microbial identification/susceptibility system since the last survey on 3/18/2021 and manufacturer's instructions for Beckman Coulter MicroScan Dried Gram Positive and Dried Gram Negative panels revealed the laboratory failed to include the recommended organisms listed below to produce positive and negative reactivity for each biochemical reagent on the new lots of PC 33 panels and NUC 73 panels listed. A. For the Gram Positive Combo 33 panel, the following recommended organisms were not included in quality control testing for the new lots listed below: (1) Lot #2022-04-22, put in use 9/29/2021: Micrococcus (M.) luteus American Type Culture Collection (ATCC) 49732 and Streptococcus (S.) pneumoniae ATCC 49136 were not included. (2) Lot #2022-11-10, put in use 3/23/2022: S. pneumoniae ATCC 49136 and Escherichia (E.) coli ATCC 35218 were not included. (3) Lot #2023-05-</p>

11, put in use 8/24/22--S. pneumoniae ATCC 49136 and E. coli ATCC 35218 were not included. B. For the Gram Negative Urine Combo 73 panel, the following recommended organisms were not included in quality control testing for the new lots listed below: (1) Lot #2022-07-28, put in use 9/29/2021: Shewanella putrefaciens ATCC 49138 was not included. (2) Lot #2022-12-15, put in use 3/23/2022: Staphylococcus (S.) aureus ATCC 29213, Enterococcus (E.) faecalis ATCC 29212, and Shewanella putrefaciens ATCC 49138 were not included. (3) Lot #2023-05-13, put in use 8/24/2022: S. aureus ATCC 29213, E. faecalis ATCC 29212, and Shewanella putrefaciens ATCC 49138 were not included.