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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>46D0666017            | <b>(X3) Date Survey Completed</b><br>08/15/2019 |
| <b>Name of Provider or Supplier</b><br>Microculture Inc  | <b>Street Address, City, State</b><br>8841 S Redwood Road Ste D3, West Jordan, UT |   |
| 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>   |
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| <b>D5413</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on laboratory hours of operation review, lack of documentation, and interview with staff, the laboratory failed to document incubator temperatures were monitored when cultures were transported from the laboratory to an overnight incubator for cultures incubating over a Saturday for Sunday readings. The laboratory incubated approximately 10 to 20 cultures overnight for final interpretation. Findings include: 1. The laboratory hours of operation were Monday 10:00 A.M. to 2:00 P.M. Tuesday through Saturday 9:00 A.M. to 3:00 P.M. 2. In an interview with staff on 08/15/2019 at approximately 5:30 P.M. the technical consultant stated at the close of business on Saturday cultures were transported using insulated storage containers with containers of water incubated at 37 degrees as temperature generators. 3. The laboratory failed to document the cultures transported for overnight incubation and reading 24 hours after inoculation for susceptibility and identification cultures were monitored for temperature continuity. 4. The technical supervisor confirmed the laboratory did not record temperatures after the close of business on Saturday.</p> |
| <b>D5471</b>              | <p>CONTROL PROCEDURES<br/>CFR(s): 493.1256(e)(1)(g)</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.

This STANDARD is not met as evidenced by:

Based on media quality control records review, procedure manual review, patient test records review, and interview with the laboratory staff, the laboratory failed to check each new lot number of Maconkey Sorbitol media for positive and negative growth prior or concurrent with patient specimen culture for 1 of 5 media types for which the laboratory procedure manual specified quality control be performed with each new lot number or shipment of media. The laboratory used Maconkey Sorbitol media for stool cultures growth. The laboratory performed approximately 3 to 6 stool cultures per month. Findings include: 1. Laboratory media quality control records review failed to include documentation the laboratory performed quality control for Maconkey Sorbitol Media for lot number 108578 shipped 03/22/2017 expiring 05/03//2017 and lot number 224678 shipped on 11/07/2017 expiring 12/19/2017. The laboratory lacked documentation they checked the lot number in use on 10/12/2017 for sterility, or growth. 2. Procedure manual review for media quality control included instructions for quality control to be performed for each new lot number or shipment of Maconkey Sorbitol media. 3. Patient test records review included a "No Growth" stool culture result for patient 17100537 (008) collected on 10/12/2017 . Stool cultures records for Maconkey Sorbitol agar also included a no growth result. 4. In an interview conducted on 08/15/2019 at approximately 5:45 P.M., the laboratory technical supervisor stated the laboratory failed to document media quality control for the shipment of media used to culture the stool specimen collected and inoculated on 10/12/2017.