| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 33D0160533 | 03/13/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sound Medical Care Pc | 516 Montauk Highway Ste 1, East Moriches, NY | |

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 |
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| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor's review of the manufacturer's packet insert for Siemens Multistix and interview with the laboratory supervisor and the testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the urine Multistix. FINDINGS: 1. The laboratory is using Siemens Multistix. The packet insert for the urine Multistix requires that external controls be performed with each new Vial of Multistix opened. 2. On March 13, 2019 at approximately 11:00 AM the laboratory supervisor and the testing person confirmed surveyor's findings that documentation for the required external control testing was not available for the current Multistix vial in use, lot # 712008, expiration date 5/31/19. 3. Approximately 50 patients specimens were tested and reported for urinalysis using the above vial Multistix. |
| **D5471** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(1)(g)<br><br>(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. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor's review of the bacteriology Quality Control (QC) documentation and an interview with the laboratory supervisor and the testing person, the laboratory failed to check each new batch, lot number and shipment of 0.04 bacitracin disc for positive and negative reactivity in calendar year 2017 through January 24, 2019. FINDINGS: 1. On March 13, 2019 at approximately 11:00 AM the laboratory supervisor and the testing person confirmed surveyor's findings that the laboratory failed to check each new batch, lot number and shipment of the bacitracin disc for positive and negative reactivity from February 2017 through January 24, 2019. 2. The laboratory failed to record the lot number/expiration date for the shipment of bacitracin disc received in the lab from February 2017 through January 24, 2019. 3. Approximately 700 patients specimens were tested and reported for throat culture during this time period. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a surveyor's review of records and confirmed in an interview with the laboratory supervisor and the testing person at the time of this survey, the laboratory failed to perform bacteriology QC as required from February 2017 through January 24, 2019. The laboratory failed to: 1. Perform and document the sterility for the Selective Strep Agar (SSA) Media; 2. Document the physical characteristics of the SSA Media for any deterioration; 3. Check each new batch, lot number and shipment of SSA Media for positive and negative reactivity. Approximately 700 patient specimens were tested and reported for throat culture during the above time period. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor findings and interview with the laboratory supervisor and the testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory maintained the laboratory's QC program for bacteriology. Refer to D6020 |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor's review of Quality Control (QC) records and confirmed, during this onsite survey with the laboratory supervisor and the testing person, the laboratory director failed to ensure that the QC program for bacteriology testing was maintained to assure quality of laboratory services. Refer to: D1001, D5471, D5477 |