

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408762	(X3) Date Survey Completed 12/01/2020
Name of Provider or Supplier Dakota Regional Medical Center Hospital Laboratory	Street Address, City, State 107 12th St S, Cooperstown, ND	
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 observation, staff interview, and policy review, the laboratory failed to perform quality control (QC) for 1 of 1 microbiology reagent (potassium hydroxide [KOH]) before use. The laboratory performed approximately 19 patient tests using the current lot number of KOH reagent since 08/06/19. Findings include: 1. Observation of the laboratory on 12/01/20 at approximately 10:45 a.m. revealed KOH reagent, lot number B01B120M, available for patient testing. 2. Upon request at approximately 5:00 p.m. on 12/01/20, the laboratory failed to provide evidence of performing QC for KOH reagent lot number B01B120M. 3. During interview at approximately 5:00 p.m. on 12/01/20, the laboratory director (#1) confirmed the laboratory had used this lot number of KOH reagent for patient testing and did not have evidence of QC performance. 4. Reviewed on 12/01/20 at 5:15 p.m., the policy "Direct KOH Examination," dated 05/2017, stated, ". . . Efficacy: Every new shipment of 10% KOH, is checked to see that it dissolves epithelial cells and preserves fungal elements. . . . Record in QA [quality assurance] Validation Log. . . ."</p>