

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0408793	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Chi Oakes Hospital	Street Address, City, State 1200 N 7th St, Oakes, 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, record review, staff interview, and procedure review, the laboratory failed to perform quality control (QC) for 1 of 1 mycology reagent (potassium hydroxide [KOH]) before use. The laboratory performed two patient tests using the current lot number of KOH reagent since 03/30/23. Findings include: 1. Observation of the laboratory on 06/21/23 at 12:25 p.m. revealed KOH reagent, lot number 430812 with an open date of 03/30/23, available for patient testing. 2. Review of the 2023 KOH patient testing record indicated the laboratory performed patient testing on 05/12/23 and 06/08/23 with the current lot number of KOH reagent. 3. Upon request on 06/21/23, the laboratory failed to provide evidence of performing QC for KOH reagent lot number 430812. 4. During interview at 12:30 p.m. on 06/21/23, the laboratory supervisor (#1) confirmed the laboratory had used this lot number of KOH reagent for patient testing and had failed to perform QC before use. 5. Reviewed on 06/21/23, the procedure "KOH Procedure," dated 05/2018, stated, ". . . Quality Control: Perform a QC when a new shipment or new lot of KOH reagent is received. . ."</p>