

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1043439	(X3) Date Survey Completed 11/02/2021
Name of Provider or Supplier Southside Community Health Services	Street Address, City, State 324 East 35th Street, Minneapolis, MN	
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
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory director failed to ensure initial training and competency assessment was performed prior to testing patient specimens for one testing personnel. Findings are as follows: 1. The laboratory performed Vaginal Wet Preparation microscopic examinations as confirmed by The Laboratory Director (LD) during a tour of the laboratory on 11/02/21 at 1:10 p.m. 2. An Abco microscope were observed as present and available for use during the tour of the laboratory. 3. Testing Personnel 1 indicated Testing Personnel 3 (TP3) was employed by the laboratory prior to the previous survey on 11/08/19. TP3 was not included on the Laboratory Personnel Report (CLIA) Form CMS-209 in 2019. 4. The Wet Prep/KOH patient testing logs indicated TP3 had performed testing of patient specimens in 2020 and 2021. See below. 2020 Month Number of tests October 3 2021 Month Number of tests May 1 June 1 5. The Technical Competency procedure located in the Laboratory Policies and Procedures manual indicated all personnel were evaluated for competency prior to working in the laboratory. 6. The Competency Assessment form for TP3 found during survey indicated the initial competency assessment was performed on 10/15/21. 7. In an interview at 2:05 p.m. on 11/02/21, the LD confirmed the above finding. .</p>

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure competency was assessed at least semi-annually during the first year of patient specimen testing for one of one testing personnel in 2021. Findings are as follows: 1. The laboratory performed Vaginal Wet Preparation microscopic examinations as confirmed by The Laboratory Director (LD) during a tour of the laboratory on 11/02/21 at 1:10 p.m. 2. An Abco microscope were observed as present and available for use during the tour of the laboratory. 3. Testing Personnel 1 (TP1) received initial competency assessment in December 2020 as indicated in personnel records. 4. The Technical Competency procedure located in the Laboratory Policies and Procedures manual indicated all personnel were evaluated for competency every six months during the first year of testing. 5. A semi-annual competency assessment for TP1 was not found during review of laboratory records. The laboratory was unable to provide the missing assessment upon request. 6. In an interview at 1:45 p.m. on 11/02/21, the LD confirmed the above finding.