

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0335176	(X3) Date Survey Completed 05/05/2022
Name of Provider or Supplier Metrohealth Broadway Central Laboratory	Street Address, City, State 6835 Broadway Avenue, Cleveland, OH	
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control (QC) documentation, and interviews with Technical Consultant (TC) #2 and Testing Personnel (TP) #5, the laboratory failed to establish and document QC activities for wet mount and potassium hydroxide (KOH) testing procedures to monitor the accuracy and precision of the complete analytic process, to include the number, type and frequency of testing control materials. All 10,628 patient wet mount and KOH testing conducted in 2020, 2021 and 2022 to date had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Broadway Satellite Laboratory - Wet Mount Procedure for Microscopic Evaluation" policy and procedure, provided on the date of the inspection, found the following statements: "D. Quality Control: 1. Visual check of saline reagent for any contamination or degradation is completed daily. 2. External quality controls for the wet mount testing are not required." 2. Review of the laboratory's "Broadway Satellite Laboratory - KOH Mount for Identification of Fungal Elements" policy and procedure, provided on the date of the inspection, found the following statements: "D. Quality Control: 1.</p>

Visual check of KOH reagent for any degradation or contamination is completed daily. Document the visual check and acceptability of the KOH reagent on the WetPrep/KOH patient log. Running of external controls material for KOH preparations are not required." 3. The Inspector requested the laboratory's wet mount and KOH QC policies and procedures and 2020, 2021 and 2022 QC testing documentation from TC#2 and TP#5. TC#2 and TP#5 confirmed the laboratory did not have external wet mount and KOH QC policies and procedures established, did not conduct and document any external wet mount and KOH QC activities in 2020, 2021 and 2022 and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 05/03/2022 at 10:32 AM.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and interviews with Technical Consultant (TC) #2 and Testing Personnel (TP) #5, the laboratory failed to ensure one out of two Technical Consultants (TC) met the qualification requirements of 493.1411 of this subpart and who provided technical oversight of the moderately complex wet mount, potassium hydroxide (KOH), urinalysis and urine microscopic testing procedures performed. All 3,580 patient wet mount, KOH, urinalysis and urine microscopic testing conducted from 09/27/2021 to 05/03/2022 to date had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to ensure one out of two individuals listed on the CMS-209 and credentialed by the Laboratory Director met the TC qualification requirements who provided technical consultation for the moderately complex wet mount, potassium hydroxide (KOH), urinalysis and urine microscopic testing procedures performed. (Refer to D6034) 2. The TC failed to evaluate and document the competency of four out of six TP in 2021 assuring their competency was maintained in order to perform moderately complex wet mount, potassium hydroxide (KOH), urinalysis and urine microscopic testing procedures and report the test results promptly, accurately, and proficiently. (Refer to D6046)

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on record review and interviews with Technical Consultant (TC) #2 and Testing Personnel (TP) #5, the laboratory failed to ensure one out of two individuals listed on the CMS-209 and credentialed by the Laboratory Director met the TC qualification requirements who provided technical consultation for the moderately

complex wet mount, potassium hydroxide (KOH), urinalysis and urine microscopic testing procedures performed. All 3,580 patient wet mount, KOH, urinalysis and urine microscopic testing conducted from 09/27/2021 and 05/03/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Competency and Performance Assessment" policy and procedure, approved, signed and dated by the Laboratory Director on 09/15/2020 and provided on the date of the inspection, found the following statement: "10. Competency Assessment Responsibility Assignment: NOTE: The CLIA laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel... * Testing personnel performing moderate complexity testing must be assessed by the CLIA Technical Consultant (moderate complexity lab), or qualifications with a Bachelor level degree." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 05/03/2022, found two individuals listed and credentialed by the Laboratory Director to perform the TC responsibilities for the moderately complex wet mount, KOH, urinalysis and urine microscopic testing procedures performed. 3. Review of the education records for TC#1 provided on the date of the inspection, revealed TC#1 achieved an Associate of Applied Science in Medical Laboratory Technology and a Bachelor of Science in Health Sciences and did not meet the minimum TC qualification requirements. 4. TC#2 and TP#5 confirmed TC#1 had assessed the competency of testing personnel who conducted wet mount, KOH, urinalysis and urine microscopic testing procedures from 09/27/2021 to 05/03/2022. The interviews occurred on 05/03/2022 at 11:45 AM. 5. The Inspector informed TC#2 via a telephone call on 05/04/2022 at 11:40 AM that it was confirmed that TP#5 did not meet the minimum TC qualification requirements. 6. The Inspector requested from TC#2 the competency assessment documentation for the TP in which TC#1 conducted in 2021 and 2022. TC#2 provided the requested competency assessment documentation on 05/05/2022 at 4:25 PM via electronic mail (email).

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
 Based on record review and interviews with Technical Consultant (TC) #2 and Testing Personnel (TP) #5, the TC failed to evaluate and document the competency of five out of seven TP in 2021 and 2022 assuring their competency was maintained in order to perform moderately complex wet mount, potassium hydroxide (KOH), urinalysis and urine microscopic testing procedures and report the test results promptly, accurately, and proficiently. All 3,580 patient wet mount, KOH, urinalysis and urine microscopic testing conducted from 09/27/2021 to 05/03/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Competency and Performance Assessment" policy and procedure, provided on the date of the inspection, found the following instructions for TP competency assessments conducted by the TC. "10. 10. Competency Assessment Responsibility Assignment: NOTE: The CLIA laboratory director must delegate, in writing, the performance of competency assessment to qualified personnel... * Testing personnel performing moderate complexity testing must be assessed by the CLIA Technical Consultant (moderate complexity lab), or qualifications with a Bachelor level degree." 2. Review of the laboratory's Form CMS-209, approved, signed, and

dated by the Laboratory Director on 05/03/2022, revealed two TC's listed and credentialed to function in the TC role and seven TP listed and credentialed by the Laboratory Director to perform moderately complex wet mount, KOH, urinalysis and urine microscopic testing procedures. 3. Review of the laboratory's 2021 competency assessment records, provided via electronic mail on 05/05/2022 at 4:25 PM, revealed the following five out of seven TP's had their competencies assessed by TP#5 (also listed on the CMS-209 as a TC) who was determined to not meet the minimum TC qualification requirements. Date TP Assessment Type 12/14/2021 TP1 Annual 12/15/2021 TP2 Annual 11/17/2021 TP3 Initial 04/08/2022 TP3 6 Month 12/10/2021 TP4 Annual 12/16/2021 Float Annual 4. The Inspector informed TC#2 via a telephone call on 05/04/2022 at 11:40 AM that it was confirmed that TP#5 did not meet the minimum TC qualification requirements. TC#2 confirmed that TP#5 was listed, credentialed and functioned as a TC and conducted TP competency assessment activities from 09/27/2021 to 05/03/2022. 5. The Inspector requested from TC#2 the competency assessment documentation for the TP in which TC#1 conducted in 2021 and 2022. TC#2 provided the requested competency assessment documentation on 05/05/2022 at 4:25 PM via electronic mail (email).