

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0326962	(X3) Date Survey Completed 02/09/2018
Name of Provider or Supplier Norton Children's Medical Group-Elizabethtown	Street Address, City, State 1301 Ring Road, Elizabethtown, KY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 02/09/2018, the laboratory director failed to follow laboratory policy and sign annual competency assessments for four of eleven employees in 2016 and 2017. Findings include: Review of the the laboratory's Quality Assessment compliance list revealed "Employee Competencies are completed initially and at 6 months for new hires, then once per year and signed by Lab Dir." Testing Personnel #1 had competencies 06/01/2016 and 05/10/2017. There was no evidence of the Laboratory Director's signatures. Testing Personnel #4 had competencies 06/01/2016 and 05/10/2017. There was no evidence of the Laboratory Director's signatures. Testing Personnel #7 had competencies 06/01/2016 and 05/09/2017. There was no evidence of the Laboratory Director's signatures. Testing Personnel #11 had competencies 06/24/2016 and 05/09/2017. There was evidence of the Laboratory Director's signatures. Testing Personnel acknowledged in an interview at 1:30 PM on 02/09/2018, the laboratory failed to have a system in place to ensure laboratory policy for competency assessment was followed.</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of personnel files and staff interview on 02/09/2018, the technical consultant failed to perform and document a semiannual competency assessment on two of eleven testing personnel responsible for moderate complex testing. Findings include: Review of the personnel file revealed Testing Personnel #3 was hired 03/26/2017. There was no evidence of a semiannual competency assessment. Review of the personnel file revealed Testing Personnel #8 was hired 03/26/2017. There was no evidence of a semiannual competency assessment. Testing personnel acknowledged in an interview at 1:30 PM on 02/09/2018, the laboratory failed to establish a system to ensure competency assessments were performed and documented at least semiannually during the first year of hire on personnel responsible for moderate complex testing.

D6054

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 annually, after the first year.

This STANDARD is not met as evidenced by:
Based on review of personnel files and staff interview on 02/09/2018, the technical consultant failed to perform and document annual competency assessments on three of eleven testing personnel. Findings include: There was no evidence of a competency assessment performed on Testing Personnel #2 in 2017. There was no evidence of a competency assessment performed on Testing Personnel #5 in 2017. There was no evidence of a competency assessment performed on Testing Personnel #6 in 2017. Staff acknowledged in an interview at 1:30 PM on 02/09/2017, the laboratory failed to have a system in place to ensure competency assessments were performed on all Testing Personnel annually.