

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D1040728	<b>(X3) Date Survey Completed</b>  10/29/2019
<b>Name of Provider or Supplier</b>  University Hospitals Avon	<b>Street Address, City, State</b>  1997 Healthway Drive, Avon, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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:</p> <p>Item I: Based on record review and an interview with the Technical Supervisor (TS) #6, the laboratory failed to follow their written policies and procedures for seven out of 47 competency assessments reviewed for testing personnel performing moderate and high complexity hematology and urinalysis procedures. This deficient practice had the potential to affect all patients tested in the speciality of hematology and subspecialty of urinalysis. Findings include: 1. Review of the laboratory's 'Competency Assessment' for testing personnel policy and procedure found the following statements: "For laboratories performing moderate complexity testing, CLIA allows the laboratory director (Medical Director) the ability to delegate the following responsibilities to those individuals meeting qualifications as a Technical Consultant and/or Technical Supervisor: - Orientation of testing personnel; and - Performance and documentation of competency assessments for those individuals performing moderate complexity tests." 2. Review of the laboratory's competency assessment documentation found the following competency assessments that were not assessed by the Technical Consultant (TC), as stated in the approved policy: Hematology: 3/28/18 TP #3 assessed by TP #8 4/11/18 TP #11 assessed by TP #8 Urinalysis: 6/2/17 TP #14 assessed by TP #8 6/11/17 TP #7 assessed by TP #8 6/12/17 TP #13 assessed by TP #8 6/8/19 TP #6 assessed by TP #8 3. An interview with TS #6, on 10/29/19 at 1:37 pm, confirmed that the lab failed to ensure the aforementioned seven out of 47 competency assessments were performed by qualified TC or TS. Item II: Based on record review and an interview with the Technical Supervisor (TS) #6, the laboratory failed to follow their written policies and</p>

procedures for annual competency assessment for one out of 14 Testing Personnel (TP) performing moderate and high complexity chemistry, hematology, immunology and urinalysis procedures. This deficient practice had the potential to affect all patients tested in the specialties of chemistry, hematology, immunology, and in the subspecialty of urinalysis. Findings include: 1. Review of the laboratory's 'Competency Assessment' policy and procedure found the following statements: "Employees must be periodically evaluated and monitored to ensure training is effective and confirm they are competent to perform laboratory testing that produces quality results. Competency assessments are performed annually based on assigned duties. All new employees must be assessed initially and semiannually for the first year of patient testing. All existing employees must be assessed initially and semiannually for the first year of patient testing following the implementation of any new Test System." 2. Review of the laboratory's competency assessment documentation found the lab failed to complete a 2018 annual competency assessment for TP #7, as stated in the approved policy. 3. An interview with TS #6, on 10/29/19 at 1:37 pm, confirmed that the lab failed to ensure a 2018 annual competency assessment was completed for TP #7.