Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0345018	02/20/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Health Harrison Medical Center	10450 New Haven Road, Harrison, 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
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to report the correct blood urea nitrogen (BUN) normal range values for five out of five patient test reports reviewed. This deficient practice had the potential to affect all patient BUN testing. Findings include: 1. Review of the laboratory's policy and procedure titled "Calibration/Calibration Verification /Validation of AMR/CRR", approved by the laboratory director on 07/13/2011 revealed the following ranges for adults over 18 years of age: Test Reference Range Units BUN 7-18 mg/dL 2. Review of five chemistry test reports found the following reference ranges listed: Test Reference Ranges Units BUN 7-20 mg/dL 3. An interview with the LM, confirmed the BUN reference range listed on the test reports were wrong. The interview occurred 02/20/2020 at 1:20 PM. mg/dL = milligrams per deciliter
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 an interview with the Laboratory Manager (LM), the Technical Supervisor (TS) failed to evaluate the competency of six out of seven testing personnel (TP) #1, #2, #3, #4, #5, and #7 to assure they maintained their competency to perform moderate and high complexity test procedures and report test results promptly, accurately, and proficiently in 2018. All patient testing performed by TP#1, #2, #3, #4, #5, and #7 in 2018 had the potential to be affected by this deficient practice. Findings include: 1. Review of the laboratory's Form CMS-209 signed by the Laboratory Director on 2/17/2020, revealed seven individuals listed as TP. 2. Review of the laboratory's "Laboratory Staff Orientation, Education, Training and Competency Assessment" policy and procedure found the following statements: "Competency of technical personnel and participation in internal and external continuing education activities will be documented in the employees education file and each employee's participation evaluated annually as part of the employee's annual performance evaluation." 3. Review of staff documents found the following hire dates: TP#1 date of hire 07/24/2017 TP#2 date of hire 09/13/2010 TP#3 date of hire 01 /02/2007 TP#4 date of hire 02/24/1992 TP#5 date of hire 07/06/2009 TP#6 date of hire 01/06/2020 TP#7 date of hire 06/17/2013 4. Review of the laboratory's competency assessment documentation, provided on the date of the inspection, found no 2018 records for TP#1, TP#2, TP#3, TP#4, TP#5, and TP#7. 5. The LM confirmed the laboratory's 2018 competency assessments for TP#1, TP#2, TP#3, TP#4, TP#5, and TP#7 were misplaced and not available for review. The interview occurred on 02 /20/2020 at 10:53 AM.