Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0330667	(X3) Date Survey Completed 11/06/2018
Name of Provider or Supplier Ohiohealth Marion Medical Campus	**Street Address, City, State** 1040 Delaware Avenue, Marion, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Item 1: Based on record review and an interview, the laboratory failed to follow written policies and procedures to assess and document the competency of the Technical Consultant and General Supervisor based on the responsibilities of the position. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of policies and procedures, on 11/6/18 at 9:47 am, found the following statement: "Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: clinical consultant (CC), technical consultant (TC), technical supervisor (TS), general supervisor (GS) and testing personnel (TP). 2. Review of the laboratory's competency documentation, on 11/6/18 at 10:58 am, found no completed competency assessment for the Technical Consultant and General Supervisor based on responsibilities of that position. 3. An interview with Technical Consultant #1, on 11/6 /18 at 11:42 am, confirmed that no competency assessment was performed for the Technical Consultant and General Supervisor based on responsibilities of that position. Item 2: Based on record review and an interview, the lab failed to follow written policies and procedures to assess and document the competency of Cytotechnologist #1. All patients tested at this lab have the potential to be affected. 1. Review of the polices and procedures on 11/6/18 at 9:47 am found the following statement: "Who can perform competency assessment? ...Testing personnel performing high complexity testing must be assessed by an individual meeting general supervisor requirements for high complexity testing..." 2. Review of competency assessment documentation for Cytotechnologist #1 found one competency

	assessment, dated on 10-17-18, completed by Anatomic Pathology Manager, who is not listed on the CMS-209 form, has a bachelor degree in business and was not qualified to perform General Supervisor duties. 3. An interview with the Anatomic Pathology Manager, on 11/6/18 at 11:49 am, confirmed that the competency assessment for Cytotechnologist #1, dated on 10-17-18, was completed by Anatomic Pathology Manager, who is not listed on the CMS-209, has a bachelor degree in business and was not qualified to perform General Supervisor duties. Item 3: Based on record review and an interview, the lab failed to follow written policies and procedures to assess and document the competency of the Cytology General Supervisor. All patients tested at this laboratory have the potential to be affected. 1. Review of the polices and procedures on 11/6/18 at 9:47 am found the following statement: "Who can perform competency assessment? ...Testing personnel performing high complexity testing must be assessed by an individual meeting general supervisor requirements for high complexity testing..." 2. Review of competency assessment documentation for the Cytology General Supervisor found 2016-2018 competency assessment completed by Cytotechnologist #1, who was not qualified to perform General Supervisor duties. 3. An interview with the Anatomic Pathology Manager, on 11/6/18 at 11:57 am, confirmed that the 2016-2018 competency assessment for Cytology General Supervisor was completed by Cytotechnologist #1, who was not listed as the Cytology General Supervisor on the CMS-209 form to perform Cytology General Supervisor duties.
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, the laboratory failed to report the correct reference interval for the International Normalized Ratio (INR), for six out of six patients, as determined by the laboratory and approved by the Laboratory Director. Findings Include: 1. Review of the laboratory's established reference ranges listed the INR reference range: "INR 0.9 -1.1." 2. Review of six of the laboratory's patient test reports from 2017 and 2018, found the following reported reference interval: Patient #1: "INR 0.9 (0.8-1.1)" Patient #2: "INR 1.4 (0.8-1.1)" Patient #3: "INR 1.1 (0.8-1.1)." Patient #4: "INR 1.0 (0.8-1.1)" Patient #5: "INR 2.8 (0.8-1.1)" Patient #6: "INR 1.1 (0.8-1.1)" 3. An interview with Technical Consultant (TC) #1, on 11/6/18 at 2:23 pm, confirmed that the lab failed to report the correct reference interval for the INR on patient test report.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview, the Technical Supervisor (TS) failed to

	provide technical supervision and ensure that the Cytology General Supervisor maintained their competency to perform test procedures and report accurate test results. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. The TS failed to evaluate and document the 2016-2018 competency of the Cytology General Supervisor who was responsible for high complexity Cytology testing. (Refer to D6128.) 2. An interview with the Anatomic Pathology Manager, on 11/6/18 at 11:57 am, confirmed that the TS failed to evaluate and document the 2016-2018 competency assessments for the Cytology General Supervisor.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on record review and an interview, the Technical Supervisor (TS) failed to evaluate and document the competency of the Cytology General Supervisor, responsible for high complexity testing, at least annually after the first year. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of competency assessment documentation found that Cytotechnologist #1, and not the TS as required, completed the competency assessment of the Cytology General Supervisor from 2016-2018. 2. An interview with the Anatomic Pathology Manager, on 11/6/18 at 11:57 am, confirmed that TS failed to evaluate and document the competency of the Cytology General Supervisor from 2016-2018.