

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 16D1076651 | (X3) Date Survey Completed 09/24/2019 |
| Name of Provider or Supplier Iowa Clinic Pathology Laboratory, The | Street Address, City, State 5950 University Avenue, West Des Moines, IA | |
| 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 |
|---------------------------|--|
| D5215 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and confirmed by the Laboratory Administrator at approximately 11:45 am on 09/24/2019, the laboratory failed to perform a self evaluation of ungraded PT scores for four out of four PT testing events in 2018 and 2019 (2018 events 1 and 2 and 2019 events 1 and 2). The findings include: 1. For 2018 testing event 1, the laboratory received ungraded PT test scores for the following: *HER2-A 2018 HER2 Immunohistochemistry Survey- Core 05, specimen HER2-02 (Score 3+) 2. For 2018 testing event 2, the laboratory received ungraded PT test scores for the following: *HER2-B 2018 HER2 Immunohistochemistry Survey- Core 04, specimen HER2- 03 (Score 3+) 3. For 2019 testing event 1, the laboratory received ungraded PT test scores for the following: *HER2-A 2019 HER2 Immunohistochemistry Survey- Core 09, specimen HER2-01 (Score 3+) *HER2-A 2019 HER2 Immunohistochemistry Survey- Core 10, specimen HER2-02 (Score 0) 4. For 2019 testing event 2, the laboratory received ungraded PT test scores for the following: *HER2-B 2019 HER2 Immunohistochemistry Survey- Core 07, specimen HER2-04 (Score 1+) 4. At the time of the survey, the laboratory did not have additional documentation or corrective action for the ungraded PT test scores.</p> |
| D5629 | <p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> |

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:

Based on review of written policies and procedures, cytology statistic records, and confirmed by laboratory personnel identifiers #3 and #4 (refer to the Laboratory Personnel Report) at approximately 2:30 pm on 09/24/2019, the laboratory failed to document an annual statistical evaluation including: the number of cytology cases examined (gynecologic and non-gynecologic); the number of specimens processed by specimen type (gynecologic and non-gynecologic); patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) (gynecologic and non-gynecologic); gynecologic cases with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; gynecologic cases where cytology and histology are discrepant; and gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms for 2017 and 2018.

D5639

CYTOLOGY

CFR(s): 493.1274(d)(2)(i)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the Following: (d)(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition-- (d)(2)(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

This STANDARD is not met as evidenced by:

Based on review of policies and procedures, slide review records, and confirmed by the Laboratory Administrator at approximately 2:00 pm on 09/24/2019, the laboratory failed to follow written policies and procedures that ensure the maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (gynecologic, non-gynecologic, or both), irrespective of the site or laboratory, for one out of one part-time cytotechnologist (laboratory personnel identifier #8, refer to the Laboratory Personnel Report) and three out of six days (09/11/2018, 09/12/2018, and 09/17/2018) in September 2018. The findings include: 1. The Laboratory Administrator stated that personnel identifier #8 works part-time for The Iowa Clinic

Pathology Laboratory (Laboratory A) and holds full-time employment with another laboratory (Laboratory B). 2. Laboratory A's "Workload Limits and Documentation" policy stated the following: "The maximum number of slides to be examined in a 24-hour period is 100 slides." It also stated, "For each 24-hour period, each individual maintains a record of the number of gynecologic slides examined, the number of QC slides examined, the number of previously screened slides reviewed, the number of non-gynecologic slides examined, and the number of ECC cytobrush slides examined. The individual also documents the amount of time spent at the microscope examining these slides. Any work done by that individual at another laboratory is also documented in the same manner." 3. Personnel identifier #8 provides Laboratory A with a "Cytology Screening Record" completed while working at Laboratory B. 4. Slide review records for 09/11/2018 indicated that personnel identifier #8 examined 9 slides at Laboratory A and 94.5 slides at Laboratory B for a total of 103.5 slides. 5. Slide review records for 09/12/2018 indicated that personnel identifier #8 examined 6 slides at Laboratory A and 111 slides at Laboratory B for a total of 117 slides. 6. Slide review records for 09/17/2018 indicated that personnel identifier #8 examined 5 slides at Laboratory A and 108.5 slides at Laboratory B for a total of 113.5 slides.

D5641

CYTOLOGY
CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's workload limit procedure, individual workload limit worksheets, and confirmed by the Laboratory Administrator at approximately 1:00 pm on 09/24/2019, the laboratory failed to establish and follow written policies and procedures that ensure that workload limits are established and the number of slides examined prorated based on an 8-hour workday for two out of two full-time cytotechnologists (identifiers #3 and #4, refer to the Laboratory Personnel Report) with duties other than cytology slide examination and one out of one part-time cytotechnologist (identifier #8). The findings include: 1. The Laboratory Administrator stated that personnel identifiers #3 and #4 are responsible for performing duties other than screening cytology slides. 2. The Laboratory Administrator also stated that personnel identifier #8 works part-time at the Iowa Clinic Pathology Laboratory (Laboratory A) and full-time in another laboratory (Laboratory B). 3. The laboratory's "Workload Limits and Documentation" policy stated the following: "The Technical Supervisor will use the following formula as a tool to set the workload limits (this only serves as an aid as the number of hours worked per cytotechnologist varies day to day): (Number of hours worked x 100)/8. PRN cytotechnologists who primarily do QC screening will be assessed using the above formula to determine workload limits." 3. Review of the individual workload limit worksheets confirmed that the laboratory based workload limit assessments for personnel identifiers #3, #4, and #8 on a maximum of 100 cytology slides in a 24-hour period, screened in an 8-hour period, as stated in the laboratory's policy. 4. At the time of the survey, the Laboratory Administrator confirmed that the laboratory did not

establish and follow written policies and procedures to prorate the number of slides that may be examined by personnel identifiers #3 and #4 on days when other laboratory duties are performed in addition to cytology slide screening or for personnel identifier #8 on days when cytology slides are examined at both Laboratory A and Laboratory B.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:

A. Based on review of policies and procedures, lack of slide review records, and confirmed by the Laboratory Administrator at approximately 2:00 pm on 09/24/2019, the laboratory failed to follow written policies and procedures in relation to the documentation of workload limits. In addition, the laboratory failed to maintain records of the total number of cytology slides examined and the number of hours spent examining slides during each 24 hour period (irrespective of the site or laboratory) for two out of five testing personnel from 01/01/2019- 09/24/2019. The findings include: 1. The Laboratory Administrator stated that personnel identifiers #1-#4 and #8 (refer to the Laboratory Personnel Report) each examine cytology slides for the laboratory. 2. The laboratory's "Workload Limits and Documentation" policy stated the following: "For each 24-hour period, each individual maintains a record of the number of gynecologic slides examined, the number of QC slides examined, the number of previously screened slides reviewed, the number of non-gynecologic slides examined, and the number of ECC cytobrush slides examined. The individual also documents the amount of time spent at the microscope examining these slides. Any work done by that individual at another laboratory is also documented in the same manner." 3. At the time of the survey, the Laboratory Administrator confirmed that the laboratory did not have records of the total number of cytology slides examined and the time spent examining them available for personnel identifiers #1 and #2 from 01/01/2019- 09/24/2019. B. Based on review of policies and procedures, slide review records, and confirmed by the Laboratory Administrator at approximately 2:00 pm on 09/24/2019, the laboratory failed to follow written policies and procedures in relation to the documentation of workload limits. In addition, the laboratory failed to maintain records of the total number of cytology slides examined and the number of hours spent examining slides during each 24 hour period (irrespective of the site or laboratory) by one out of one part-time cytotechnologist for nine out of nine days from 01/01/2019- 09/24/2019. The findings include: 1. The Laboratory Administrator stated that personnel identifier #8 (refer to the Laboratory Personnel Report) works part-time for The Iowa Clinic Pathology Laboratory (Laboratory A) and holds full-time employment with another laboratory (Laboratory B). 2. Laboratory A's "Workload Limits and Documentation" policy stated the following: "For each 24-hour period, each individual maintains a record of the number of gynecologic slides examined, the number of QC slides examined, the number of previously screened slides reviewed, the number of non-gynecologic slides examined, and the number of ECC cytobrush slides examined. The individual also documents the amount of time spent at the microscope examining these slides. Any work done by that individual at

another laboratory is also documented in the same manner." 3. Slide review records for personnel identifier #8 from 01/01/2019- 09/24/2019 indicated that cytology slides were examined at Laboratory A on the following dates: 06/03/2019 (9 quality control [QC] slides), 06/04/2019 (4 QC slides), 06/05/2019 (5 QC slides), 06/06/2019 (5 QC slides), 06/12/2019 (3 QC slides), 06/13/2019 (5 QC slides), 06/14/2019 (8 QC slides), 06/17/2019 (6 QC slides), and 06/18/2019 (3 QC slides). The records did not specify how many hours were spent examining slides for any of the dates previously listed. 4. Personnel identifier #8 provides Laboratory A with a "Cytology Screening Record" completed when working at Laboratory B. 5. For each of the dates on which personnel identifier #8 examined slides at Laboratory A, cytology slides were also examined at Laboratory B. The number of slides and hours examining them were documented on the June 2019 "Cytology Screening Record" from Laboratory B as the following: 06/03/2019 (7 screen hours, 88.5 total slides), 06/04/2019 (7 screen hours, 62 total slides), 06/05/2019 (7 screen hours, 59 total slides), 06/06/2019 (7 screen hours, 65.5 total slides), 06/12/2019 (6 screen hours, 69.5 total slides), 06/13/2019 (7 screen hours, 73.5 total slides), 06/14/2019 (7 screen hours, 65.5 total slides), 06/17/2019 (7 screen hours, 87 total slides), and 06/18/2019 (7 screen hours, 63 total slides). 6. At the time of the survey, additional records documenting the total number of cytology slides examined and the total number of hours spent examining slides during each 24 hour period for both Laboratory A and Laboratory B were not available.