Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2271107	08/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Goldfinch Laboratory	4637 121st St, Urbandale, 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
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on lack of policies and procedures, lack of workload limit records, and confirmed by interview with General Supervisor #1 (GS #1) at 1:25 pm on 08/03/2026, the technical supervisor failed to establish a maximum workload limit for four out of four individuals who perform primary screening of non-gynecological cytology specimens from 06/01/2025- 08/03/2026. In addition, the laboratory failed to establish and follow written policies and procedures to establish maximum workload limits for individuals who perform primary screening. The findings include: 1. The laboratory began reading and reporting non-gynecological cytology cases in June 2025. 2. GS #1 stated that TS #1- TS #4 perform primary screening of non-gynecological cytology specimens. 3. At the time of the survey, GS #1 confirmed that the technical supervisor failed to establish maximum workload limits for TS #1- TS #4 from 06/01/2025- 08/03/2026. In addition, GS #1 confirmed that the laboratory failed to establish and follow written policies and procedures to establish maximum workload limits for individuals who perform primary screening.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by:

	Based on lack of policies and procedures, lack of workload limit records, and confirmed by interview with General Supervisor #1 (GS #1) at 1:25 pm on 08/03 /2026, the Technical Supervisor failed to reassess and adjust, when necessary, a maximum workload limit at least every six months for four out of four individuals who performed primary screening of nongynecologic cytology specimens and two out of two time periods from 06/01/2025- 06/30/2026. In addition, the laboratory failed to establish and follow written policies and procedures to reassess and adjust maximum workload limits at least every six months for individuals who perform primary screening. The findings include: 1. The laboratory began reading a reporting non-gynecological cytology cases in June 2025. 2. GS #1 stated that TS #1- TS #4 perform primary screening of non-gynecological cytology specimens. 3. The laboratory did not establish workload limits for primary screeners TS #1- TS #4. Refer to the standard D5633. 4. At the time of the survey, GS #1 confirmed that the laboratory failed to have documentation that the Technical Supervisor reassessed the workload limit at least every six months for primary screeners TS #1- TS #4 from 06/01/2025- 06/30 /2026. In addition, GS #1 confirmed that the laboratory failed to establish and follow written policies and procedures to reassess and adjust maximum workload limits at least every six months for individuals who perform primary screening.
D5639	CYTOLOGY CFR(s): 493.1274(d)(2)(i) (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 lack of policies and procedures, lack of slide review records, and confirmed by interview with General Supervisor #1 (GS #1) at 1:25 pm on 08/03/2026, the laboratory failed to ensure the maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides for four out of four individuals who perform primary screening of non-gynecological cytology specimens from 06/01 /2025- 08/03/2026. In addition, the laboratory failed to establish and follow written policies and procedures to ensure that the number of slides examined in each 24-hour period does not exceed 100 slides for individuals who perform primary screening. The findings include: 1. The laboratory began reading and reporting non-gynecological cytology cases in June 2025. 2. GS #1 stated that TS #1- TS #4 perform primary screening of non-gynecological cytology specimens. 3. At the time of the survey, GS #1 confirmed that the laboratory failed to have documentation of the total number of slides examined in each 24-hour period for primary screeners TS #1- TS #4 from 06 /01/2025- 08/03/2026. In addition, GS #1 confirmed that the laboratory failed to establish and follow written policies and procedures to ensure that the number of slides examined in each 24-hour period does not exceed 100 slides for individuals who perform primary screening.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (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 lack of policies and procedures, lack of workload limits, lack of slide review records, and confirmed by interview with General Supervisor #1 (GS #1) at 1:25 pm on 08/03/2026, the laboratory failed to ensure the establishment of workload limits and the number of slides examined prorated based on an 8-hour workday for for four out of four individuals who perform primary screening of non-gynecological cytology specimens from 06/01/2025- 08/03/2026. In addition, the laboratory failed to establish and follow written policies and procedures that ensure the number of slides examined are prorated based on an 8-hour workday for individuals who perform primary screening. The findings include: 1. The laboratory began reading and reporting non-gynecological cytology cases in June 2025. 2. GS #1 stated that TS #1- TS #4 perform primary screening of non-gynecological cytology specimens, reading and reporting of histopathology cases, and perform duties other than slide examination on a daily basis. 3. The laboratory did not establish workload limits for primary screeners TS #1- TS #4. Refer to the standard D5633. 4. At the time of the survey, GS #1 confirmed that the laboratory failed to have documentation of slide review records with the number of slides examined prorated based on an 8-hour workday for TS #1- TS #4. In addition, GS #1 confirmed that the laboratory failed to establish and follow written policies and procedures that ensure the number of slides examined are prorated based on an 8-hour workday for individuals who perform primary screening.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (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: Based on lack of policies and procedures, lack of slide review records, and confirmed by interview with General Supervisor #1 (GS #1) at 1:25 pm on 08/03/2026, the laboratory failed to maintain records of the total number of slides examined during each 24-hour period and the number of hours spent examining slides for four out of four individuals who perform primary screening of non-gynecological cytology specimens from 06/01/2025- 08/03/2026. In addition, the laboratory failed to establish and follow written policies and procedures to ensure maintenance of records of the total number of slides examined during each 24-hour period and the number of hours spent examining slides for individuals who perform primary screening. The findings include: 1. The laboratory began reading and reporting non-gynecological cytology cases in June 2025. 2. GS #1 stated that TS #1- TS #4 perform primary screening of non-gynecological cytology specimens. 3. At the time of the survey, GS #1 confirmed that the laboratory failed to have documentation of the total number of slides examined during each 24-hour period and the number of hours spent examining slides for primary screeners TS #1- TS #4 from 06/01/2025- 08/03/2026. In addition, GS #1 confirmed that the laboratory failed to establish and follow written policies and

	procedures to ensure maintenance of records of the total number of slides examined during each 24-hour period and the number of hours spent examining slides for individuals who perform primary screening.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d)(4) Records are available to document the workload limit for each individual. (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: This STANDARD is not met as evidenced by: Based on lack of policies and procedures, lack of workload limit records, and confirmed by interview with General Supervisor #1 (GS #1) at 1:25 pm on 08/03 /2026, the laboratory failed to ensure availability of records to document the workload limit for four out of four individuals who perform primary screening of non-gynecological cytology specimens from 06/01/2025- 08/03/2026. In addition, the laboratory failed to establish and follow written policies and procedures to ensure records are available to document the workload limit for each individual who performs primary screening. The findings include: 1. The laboratory began reading and reporting non-gynecological cytology cases in June 2025. 2. GS #1 stated that TS #1- TS #4 perform primary screening of non-gynecological cytology specimens. 3. The laboratory failed to establish workload limits for primary screeners TS #1- TS #4. Refer to the standard D5633. 4. At the time of the survey, GS #1 confirmed that the laboratory failed to ensure availability of records to document the workload limit for primary screeners TS #1- TS #4 from 06/01/2025- 08/03/2026. In addition, GS #1 confirmed that the laboratory failed to establish and follow written policies and procedures to ensure records are available to document the workload limit for each individual who performs primary screening.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory personnel records and confirmed by interview with General Supervisor #1 (GS #1) at 10:20 am on 08/03/2026, the laboratory failed to meet the testing personnel requirements by providing documentation to qualify the testing personnel who perform high complexity testing as specified in standard D6171. This is a repeat deficiency, previously cited on 08/16/2024.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical

	laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and confirmed by interview with General Supervisor #1 (GS #1) at 10:20 am on 08/03/2026, the laboratory failed to ensure 1 out of 10 testing personnel met the educational requirements to perform high complexity testing. The findings include: 1. Testing Personnel #2 (TP #2) performed grossing of tissues, which is considered high complexity testing. 2. TP #2 did not meet the minimum semester hours required to perform high complexity testing. This is a repeat deficiency, previously cited on 08/16/2024.