

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1024082	(X3) Date Survey Completed 12/12/2018
Name of Provider or Supplier Professional Diagnostics Inc	Street Address, City, State 3580 W 9000 S, W Jordan, UT	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a policy and procedure manual and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish safety procedures to ensure protection from physical, chemical and electrical hazards, and necessary precautions to ensure safety from biohazardous materials. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to address the current physical, chemical and electrical hazards, and biohazardous materials. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.</p>
D5032	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of laboratory procedure manual, record review and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written</p>

policies and procedures to ensure positive identification and optimum integrity of cytology patient specimens from the time of collection or receipt of the specimen through reporting of test results (refer to D5203); failed to establish written policies and procedures for the documentation of complaints reported to the laboratory (refer to D5205); failed to establish written policies and procedures to document the requirements for specimen collection, specimen slide and test request slip labeling, conditions for the transportation of specimen slides and test request slips to and from the laboratory, specimen processing, specimen acceptability and rejection (refer to D5311); failed to ensure that a written policy and procedure manual for all cytology tests and examinations performed by Facility A (CLIA #46D1024082) was available to laboratory personnel (refer to D5401); failed to ensure that the required maintenance for one Becton Dickinson (BD) PrepStain Slide Processor was performed, as specified by the manufacturer (refer to D5429); failed to establish written policies and procedures for the evaluation and comparison of three of three required statistics for nongynecologic cytology, and failed to document three of three required annual statistics for 2016 and 2017 (refer to D5629); failed to establish written policies and procedures for establishing workload limits, reassessing workload limits, prorating workload limits and maintaining workload slides and hours (refer to D5633, D5637, D5641, D5645); failed to establish written policies and procedures to ensure nongynecologic cytology test reports contained narrative descriptive nomenclature (refer to D5657); failed to establish written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report (refer to D5659); failed to maintain the identity of the personnel who performed the required maintenance on the BD PrepStain Slide Processor (refer to D5787); and failed to ensure that final test reports indicated the name and address of the laboratory location where the test was performed (refer to D5805). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY
 CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:
 Based on the lack laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures to ensure positive identification and optimum integrity of cytology patient specimens from the time of collection or receipt of the specimen through reporting of test results. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to ensure positive identification and optimum integrity of cytology patient specimens from the time of collection or receipt of the specimen through reporting of test results. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5205

COMPLAINT INVESTIGATIONS

CFR(s): 493.1233

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures for the documentation of complaints reported to the laboratory for 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures for documenting complaints made to the laboratory. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 10, 2018 at 2:10 PM, Staff A stated that if there was problem with a specimen during specimen receipt it was documented on the test requisition. 4. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director /Technical Supervisor A confirmed these findings.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. Cross refer to D5203, D5205 Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures for an ongoing mechanism to monitor and assess the quality of the general laboratory system. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures to document the requirements for specimen collection, specimen slide and test request slip labeling, conditions for the transportation of specimen slides and test request slips to and from the laboratory, specimen processing, specimen acceptability and rejection. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures describing the requirements for: a. Specimen collection of nongynecologic specimens. b. Specimen labeling and corresponding test request slip labeling, to include the description of unique patient identifiers. c. Conditions for the transportation of specimens and the corresponding test request slips to and from the laboratory. d. Specimen processing, specimen acceptability and specimen rejection. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic systems. Cross refer to D5311 Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to monitor the quality of the cytology preanalytic laboratory system. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on the lack of a policy and procedure manual and interviews it was determined that a written procedure manual for all cytology tests and examinations performed by Facility A (CLIA #46D1024082) was not available to laboratory personnel. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to

provide a written procedure manual for all cytology tests and examinations performed at Facility A. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed that Facility A (CLIA #46D1024082) did not have a procedure manual.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to ensure that the required maintenance for one BD PrepStain Slide Processor was performed, as specified by the manufacturer, for five of 12 months from January 2018 through the date of the survey. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide maintenance records for the BD PrepStain Slide Processor for five of 12 months from January 2018 through the date of the survey. Months include: - July 2018 - August 2018 - September 2018 - October 2018 - November 2018 2. During an interview on December 11, 2018 at 8:30 AM, Staff A stated that Staff B usually performed the maintenance but the laboratory could not locate the records. 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5629

CYTOLOGY
CFR(s): 493.1274(c)(5)

(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 the lack of laboratory policies and procedures, interviews and lack of laboratory records, it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures for the evaluation and comparison of three of three required statistics for nongynecologic cytology, and failed to document three of three required annual statistics for 2016 and 2017. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written

policies and procedures for an annual statistical laboratory evaluation of three required statistics for the nongynecologic specimens: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis, to include unsatisfactory. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide the three required statistics for 2016 and 2017 for Facility A (CLIA #46D1024082). 4. During an interview on December 10, 2018 at 10:45 AM, the Laboratory Director/Technical Supervisor A stated that the Facility B (CLIA #46D0523203) statistics "are all-inclusive" for Facility A (CLIA #46D1024082) and Facility B (CLIA #46D0523203). 5. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director /Technical Supervisor A confirmed these findings.

D5633

CYTOLOGY
CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (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 the lack of laboratory policies and procedures, lack of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures to ensure that a maximum workload limit was established by Technical Supervisor A for five of five Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to ensure that workload limits were established by Technical Supervisor A for five of five Technical Supervisors who performed the primary evaluation of nongynecologic cytology specimens. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 2. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide documentation that Technical Supervisor A established a maximum workload limit for the five Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. 3. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 4. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5637

CYTOLOGY
CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (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 the lack of laboratory policies and procedures, lack of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to

establish written policies and procedures to ensure that the workload limit for five of five Technical Supervisors was reassessed at least every six months and adjusted when necessary in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to ensure that workload limits for five of five Technical Supervisors were reassessed at least every six months and adjusted when necessary in 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 2. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide documentation that the workload limits for the five Technical Supervisors had been reassessed every six months for 2016, 2017 and to the date of the survey in 2018. 3. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 4. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

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 the lack of laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures to ensure that the workload limit for five of five Technical Supervisors, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated using a period of eight hours to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies or procedures to determine how to prorate the workload limit for five of five Technical Supervisors when time was spent on activities other than performing primary examinations of cytology slides. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

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:
 Based on the lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish policies and procedures to ensure that Facility A maintained records of the total number of slides examined and the number of hours spent examining slides in each 24-hour period for five of five Technical Supervisors in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to ensure that Facility A (CLIA #46D1024082) maintained workload records to document the number of slides and time spent examining slides for five of five Technical Supervisors. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E 2. The Survey Team reviewed workload records for the five Technical Supervisors from 2017 through the date of the survey in 2018. a. There were no written policies and procedures to describe how the workload records were to be completed. 3. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 4. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5657

CYTOLOGY
 CFR(s): 493.1274(e)(5)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

This STANDARD is not met as evidenced by:
 Based on the lack of laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures to ensure nongynecologic cytology test reports contained narrative descriptive nomenclature. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to describe the laboratory's nomenclature system for reporting nongynecologic cytology test results. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5659

CYTOLOGY
 CFR(s): 493.1274(e)(6)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.

This STANDARD is not met as evidenced by:
 Based on the lack of laboratory policies and procedures and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies

and procedures to ensure that corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to describe Facility A's (CLIA #46D1024082) process to ensure that corrected reports indicated the basis for the correction. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to maintain the identity of the personnel who performed the required maintenance on the BD PrepStain Slide Processor for any from January 2018 through the date of the survey. Findings include: 1. The Survey Team reviewed maintenance records for the BD PrepStain Slide Processor from January 2018 through the date of the survey. There was no documentation to indicate the identity of the personnel performing the required maintenance for any day during 2018. 2. During an interview on December 11, 2018 at 8:30 AM, Staff A stated that usually Staff B performed the maintenance and confirmed the records did not indicate the identity of the personnel performing the maintenance. 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of cytology testing. Cross refer to D5401, D5429, D5629, D5633, D5637, D5641, D5645, D5657, D5659, D5787 Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures for an ongoing mechanism to monitor and assess the quality of the analytic system. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no

procedures specific for Facility A (CLIA #46D1024082). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to ensure that 17 of 17 final test reports from 2015 through 2017 indicated the name and address of the laboratory location where the test was performed. Findings include: 1. The Survey Team reviewed 17 final test reports reported by Facility A (CLIA #46D1024082) from 2015 through 2017. Seventeen of 17 final test reports did not indicate the name and address of Facility A (CLIA #46D1024082). Reports include: - 15CJ-1 - 15CJ-40 - 15CJ-45 - 15CJ-179 - 15CJ-209 - 15CJ-221 - 15CJ-222 - 15CJ-232 - 15CJ-255 - 15CJ-274 - 15CJ-281 - 16CJ-13 - 16CJ-179 - 17CJ-30 - 17CJ-179 - 1603900859 - 1604300907 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that all of Facility A's (CLIA #46D1024082) test reports indicated that the tests were performed at Facility B (CLIA #46D0523203). 3. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that Facility A (CLIA #46D1024082) failed to establish written policies and procedures for an ongoing mechanism to ensure final test reports indicated the name and address of the laboratory location where the test was performed. Cross refer to D5805 Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures for an ongoing mechanism to ensure final test reports indicated the name and address of the laboratory location where the test was performed. 2. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 3. Facility A (CLIA #46D1024082) failed to establish an ongoing mechanism to identify final test reports that did not indicate the name and address of the laboratory location where the test

was performed. 4. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on the lack of laboratory policies and procedures, record review and interviews it was determined that Facility A (CLIA #46D1024082) failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of Facility A (CLIA #46D1024082) and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that quality assessment programs were established (refer to D6094); and failed to ensure the competency of two of two Staff performing cytology processing (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the lack of a procedure manual, review of laboratory records and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of Facility A (CLIA #46D1024082), to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D3011, D5203, D5205, D5401, D5429, D5629, D5633, D5637, D5641, D5645, D5657, D5659, D5787 and D5805

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	<p>This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5291, D5391, D5791, D5891</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain competency of two of two Staff performing cytology processing in 2017 and 2018. Findings include: 1. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of Staff performing cytology processing. 2. The Survey Team requested and Facility A (CLIA #46D1024082) failed to provide completed competency records for two of two Staff performing cytology processing in 2017 and 2018. Staff includes: - Staff A - Staff B 3. During an interview on December 10, 2018 at 10:00 AM, Technical Supervisor B stated that there were no procedures specific for Facility A (CLIA #46D1024082). 4. During an interview on December 11, 2018 at 11:00 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.</p>
<p>D6130</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> <p>(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory records and interview it was determined that Technical Supervisor A failed to establish individual workload limits and to reassess the workload limits at least every six months for five of five Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Cross Refer to D5633 and D5637</p>
<p>D9999</p>	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under</p>

the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.