

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0316753	(X3) Date Survey Completed 11/15/2023
Name of Provider or Supplier Delta Health System - The Medical Center	Street Address, City, State 1400 East Union St - Laboratory, Greenville, MS	
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
D3007	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interviews with the Histology Supervisor and the Laboratory Director/Technical Supervisor, the laboratory failed to have appropriate equipment to process non-gynecologic cytology specimens for microscopic evaluation. Findings include: 1. The procedure COLLECTION AND SUBMISSION OF GYN AND NON-GYN SPECIMENS stated under Specimen Processing: - Centrifuge specimen for 10 minutes or until a well packed cellular sediment appears at the bottom of the tube. - Sediment is smeared uniformly onto glass slides. 2. The Survey Team observed the laboratory utilized a small LABRET Clinical table-top centrifuge, Model Z100-A to concentrate the non-gynecologic cytology specimens. a. The Survey Team requested the revolutions per minute (RPM) of the centrifuge. The Histology Supervisor replied, "There was no tachometer. The centrifuge is set at setting one, two or three depending on what works best." b. The Survey Team observed on November 14, 2023 at 10:30 AM, the lack of well packed cell sediment following centrifugation of non-gynecologic specimens, which was a result of unknown and insufficient RPM to concentrate the non-gynecologic cytology specimens. 3. During an interview on November 14, 2023 at 10:30 AM these findings were confirmed by the Histology Supervisor. 4. During an interview on November 15, 2023 at 8:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of eight laboratory policies and procedures, observation, review of non-gynecologic cytology slide preparations and interviews with the Laboratory Director/Technical Supervisor and the Histology Supervisor, the laboratory failed to establish and follow written policies and procedures for five laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for how a fine needle aspiration (FNA) is submitted. 2. The Survey Team requested and the laboratory failed to provide step by step written policies and procedures for the staining process for non-gynecologic cytology slide preparations. a. There were no processing times for: - a. Bluing Reagent - b. 80% alcohol - c. FLEX 95 - d. EA-36 - e. 100% Alcohol - f. Americlear b. The procedure for staining non-gynecologic cytology slide preparations included steps at the end which were redundant but these steps were not repeated during the staining process. These included: - 18. Differentiate in 2 changes of FLEX 95 - 19. Dehydrate in 4 changes of 100% Alcohol - 20. Clear in 4 changes of Americlear - 21. Mount with FloTexx, cover glass, affix label and deliver to Pathologist on service. c. During an interview on November 13, 2023 at 3:00 PM these findings were confirmed by the Histology Supervisor. 3. The laboratory failed to provide pertinent literature references for five of eight written policies and procedures. a. Procedures include: - QA Cyto Gyn - Competency Assessment for Pathologist /Technical Supervisor - Collection and Submission of Gyn and Non-gyn Specimens - Assessment of Analytical Testing Activities in the Cytology Laboratory - Monitoring, Assessing and Correcting Pre-analytic Systems for the Cytology Laboratory 4. The Survey Team requested and the laboratory failed to provide written policies and procedures for the calibration and calibration verification for the centrifuge used in the concentration of non-gynecologic cytology specimens. a. During an interview on November 14, 2023 at 10:30 AM these findings were confirmed by the Histology Supervisor. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for the application of mounting media and cover glass for the preservation and storage of stained non-gynecologic cytology slide preparations. a. The Histology Supervisor demonstrated the laboratory's method of applying mounting media and cover glass to non-gynecologic cytology slide preparations at 10:30 AM on November 14, 2023. b. The Survey Team observed that the Americlear clearing agent remained on the slide prior to adding mounting media

and the cover glass. The laboratory failed to include in a written policy or procedure that the Americlear was to be removed or drained off of the slide prior to adding the mounting media. - The clearing agent which remained on the slide diluted the mounting media and after evaporating, left large air bubbles of trapped air on the slide under the coverslip. - This resulted in an inability to microscopically visualize cellular detail on the non-gynecological cytology slide preparations. c. The Survey Team identified 62 of 258 non-gynecological cases from January 2021 to November 2023 that could not be microscopically examined due to the obscuring, large air bubbles on the specimen slide. Cases include: - CY21-10 - CY21-11 - CY21-12 - CY21-13 - CY21-14 - CY21-15 - CY21-16 - CY21-17 - CY21-18 - CY21-19 - CY21-20 - CY21-21 - CY21-45 - CY21-55 - CY21-65 - CY21-88 - CY21-89 - CY21-90 - CY22-01 - CY22-02 -CY22-03 - CY22-04 - CY22-05 - CY22-07 - CY22-08 - CY22-09 - CY22-11 - CY22-14 - CY22-18 - CY22-20 - CY22-21 - CY22-22 - CY22-23 - CY22-28 - CY22-29 - CY22-30 - CY22-35 - CY22-36 - CY22-37 - CY22-38 - CY22-40 - CY22-44 - CY22-46 - CY22-51 - CY22-58 - CY22-61 - CY22-67 - CY22-74 - CY22-81 - CY23-27 - CY23-29 - CY23-30 - CY23-41 - CY23-46 - CY23-47 - CY23-48 - CY23-50 - CY23-55 - CY23-58 - CY23-61 - CY23-67 - CY23-74 d. During an interview on November 15, 2023 at 8:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.

D5655

CYTOLOGY
CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, non-gynecologic cytology slide preparations, corresponding final test reports and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report 10 of 12 unsatisfactory non-gynecologic cytology cases from January 2021 to November 2023 as "Unsatisfactory for Evaluation." Findings include:
1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The laboratory failed to identify and report seven of 12 non-gynecologic cytology cases from January 2021 to November 2023 as being Unsatisfactory for Evaluation due to insufficient cellularity. (refer to D6115) Cases include: - CY21-80 - CY21-95 - CY21-98 - CY22-45 - CY23-17 - CY23-39 - CY23-60 3. The laboratory failed to identify and report three of 12 non-gynecologic cytology cases from January 2021 to November 2023 as being "Unsatisfactory for Evaluation" due to obscuring blood. (refer to D6115) Cases include: - CY21-57 - CY22-11 - CY22-21 4. During an interview on November 15, 2023 at 8:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.

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:

A. Based on review of laboratory policies and procedures, observation, non-gynecologic cytology slide preparations, laboratory records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified with the preparation of non-gynecologic cytology specimen slides. The laboratory failed to document quality assessment activities related to improperly prepared and scanty cellular non-gynecologic cytology specimen slide preparations during the microscopic examination of the specimen slides. Findings include: 1. The written policy and procedure COLLECTION AND SUBMISSION OF GYN AND NON-GYN SPECIMENS stated: "Specimen processing: - Record general characteristics of material including volume, color and viscosity. - Centrifuge specimen for 10 minutes or until a well packed cellular sediment appears at the bottom of the tube. - Sediment is smeared uniformly onto glass slides. - If sufficient sediment remains after making smears, cover with 95% alcohol and process as a cell block." 2. The Survey Team observed on November 14, 2023 at 10:30 AM, the specimen processing of non-gynecologic cytology slide preparations and cell blocks. a. The non-gynecologic specimens were centrifuged on a small LABRET Clinical table-top centrifuge, Model Z100-A. The centrifuge did not have a display for showing the centrifugal force or RPM's so the force was unknown. b. The centrifugal force used by the laboratory failed to provide a well packed cellular sediment during centrifugation due to insufficient centrifugal force. This resulted in a limited amount of cellular material for representative cells on the non-gynecologic cytology slide preparations. 3. The Survey Team identified 29 of 113 negative non-gynecologic cases that had scant cellularity of representative cells on the non-gynecologic cytology slide preparations from January 2021 to the date of the survey in 2023. Cases include: - CY21-21 - CY21-34 - CY21-52 - CY21-65 - CY21-100 - CY22-03 - CY22-06 - CY22-08 - CY22-12 - CY22-25 - CY22-60 - CY23-09 - CY23-11 - CY23-16 - CY23-19 - CY23-30 - CY23-44 - CY23-47 - CY23-48 - CY23-54 - CY23-63 - CY23-64 - CY23-68 - CY23-72 - CY23-73 - CY23-80 - CY23-86 - CY23-89 - CY23-90 4. The Survey Team identified seven of 113 negative non-gynecologic cases that were unsatisfactory due to scant cellularity from January 2021 to the date of the survey in 2023. Cases include: - CY21-80 - CY21-95 - CY21-98 - CY22-45 - CY23-17 - CY23-39 - CY23-60 5. The Survey Team examined 341 non-gynecologic cytology slide preparations from 113 negative non-gynecologic cytology cases from January 2021 to the date of the survey in 2023. a. The Survey Team identified 42 non-gynecologic cytology slide preparations from 21 negative non-gynecologic cytology cases that were acellular on the centrifuge-prepared slides but contained cells on the cell block preparations. Cases include: - CY21-34 - CY21-65 - CY22-03 - CY22-14 - CY22-16 - CY22-31 - CY22-45 - CY22-60 - CY23-03 - CY23-14 - CY23-16 - CY23-23 - CY23-30 - CY23-31 - CY23-47 - CY23-48 - CY23-64 - CY23-68 - CY23-80 - CY23-83 - CY23-86 b. A review of the corresponding laboratory records and final test reports did not document the identification or cause of the unsatisfactory or limited cellularity on the 42 non-gynecologic cytology slide preparations. 6. During an interview on November 15, 2023 at 8:30 AM the Laboratory Director/Technical Supervisor confirmed these findings. B. Based on review of laboratory policies and procedures, non-gynecologic cytology slide preparations, laboratory records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to

document quality assessment activities related to poorly preserved, scanty cellular and nondiagnostic non-gynecologic cytology slide preparations from January 2021 to the date of the survey in 2023. Findings include: 1. The Survey Team identified 62 of 258 non-gynecologic cytology cases from January 2021 to November 2023 that could not be examined microscopically due to large air bubbles under the cover glass. (refer to D5403) a. The laboratory failed to monitor and assess the cause and occurrence of large air bubbles. b. The laboratory failed to document quality assessment activities to address the cause and occurrence of large bubbles and poorly preserved non-gynecologic slide preparations. 2. During an interview on November 15, 2023 at 8:30 AM the Laboratory Director/Technical Supervisor 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 review of laboratory policies and procedures, laboratory records, non-gynecologic cytology specimen slide preparations, observation and interviews, the laboratory 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 ensure that the cytology specimen processing test methodologies yielded non-gynecologic cytology slide preparations with the quality needed for microscopic evaluation (refer to D6085); failed to ensure quality assessment programs were established and followed to assure the quality of analytic cytology services and identify failures in quality as they occur (refer to D6094); and failed to ensure written policies and procedures were established and followed to assess, monitor and maintain the competency of the Technical Supervisor and the Histology Supervisor (refer to D6103).

D6085

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)

The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records, non-gynecologic cytology slide preparations, observation and interview with the Laboratory Director/Technical Supervisor, the Laboratory Director failed to ensure the processing test methodologies for non-gynecologic cytology specimens provided representative and sufficient numbers of cellular material for microscopic examination, reporting and storage of non-gynecologic cytology slide preparations. Findings include: 1. The Laboratory Director failed to establish and follow written policies and procedures to ensure the processing test methodologies for non-gynecologic cytology specimens provided representative and sufficient numbers of cellular material for microscopic examination and reporting of non-gynecologic cytology slide preparations. (refer to D5403) a. The Laboratory Director failed to establish and follow written policies and procedures for the staining process of non-

gynecologic cytology slide preparations to ensure appropriate staining times for the visualization of specimen cellular material. b. The Laboratory Director failed to establish and follow written policies and procedures for the calibration and calibration verification for the centrifuge used in the concentration of non-gynecologic cytology specimens prior to specimen slide preparation. c. The Laboratory Director failed to provide the appropriate equipment for the centrifugation and concentration of cytology specimens to ensure representative and sufficient numbers of cellular material for microscopic examination and reporting of non-gynecologic cytology specimens. (refer to D3007) 2. The Laboratory Director failed to establish and follow a written policy and procedure to ensure the processing test methodologies for non-gynecologic cytology specimens provided for proper storage and preservation of non-gynecologic cytology slide preparations. (refer to D5401) a. The Laboratory Director failed to establish and follow written policies and procedures for the process of application of clearing agent, mounting media and cover glass to preserve and store the stained non-gynecologic cytology slide preparations to prevent the formation of large air bubbles under the cover glass. 3. During an interview on November 15, 2023 at 8:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records, non-gynecologic cytology slide preparations, observation and interview, the Laboratory Director failed to ensure quality assessment programs were established and maintained to assure the quality of analytic cytology services and identify failures in quality as they occur in 2021, 2022 and January 2023 to the date of the survey in 2023. Findings include: 1. The Laboratory Director failed to establish and maintain quality assessment programs to assure the quality of analytic cytology services and identify failures in quality as they occur in 2021, 2022 and January to the date of the survey in 2023. (refer to D5791) 2. During an interview on November 15, 2023 at 8:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records, review of

non-gynecologic cytology slide preparations, observation and interviews, the Laboratory Director failed to ensure written policies and procedures were established and followed to assess, monitor and maintain the competency of the Technical Supervisor and the Histology Supervisor when performing cytology duties. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established and followed to monitor and assess the duties and competency of the Technical Supervisor, and when necessary identify methods to improve the skills of the Technical Supervisor. a. The Laboratory Director failed to monitor and assess the laboratory-assigned diagnostic duties of the Technical Supervisor on the laboratory's annual COMPETENCY BASED ORIENTATION -TECHNICAL SUPERVISOR PATHOLOGY form. b. The Laboratory Director failed to monitor and assess training needs for the Technical Supervisor to evaluate and report non-gynecologic cytology specimens proficiently to include: -the identification of specimens positive for malignancy. -the identification of specimens that are "Unsatisfactory for Evaluation." - the identification of 11 of 113 negative non-gynecologic cases from January 2021 through October 2023 that were not reported accurately by the Technical Supervisor. (refer to D6115) c. The Laboratory Director failed to monitor and assess the competency of the Technical Supervisor's laboratory-assigned duty to identify and correct improperly processed non-gynecologic cytology specimen slides. 2. The Laboratory Director failed to ensure written policies and procedures were established to assess the competency of the Histology Supervisor and when necessary identify methods to improve the skills of the Histology Supervisor. a. The Laboratory Director failed to identify training needs for the Histology Supervisor when performing non-gynecologic cytology processing and slide preparation. (refer to D5403 and D5791) b. The Laboratory Director failed to monitor, assess, observe and validate the Histology Supervisor's cytology processing duties on the laboratory's annual COMPETENCY BASED ORIENTATION -HISTOLOGY TECHNICIAN form, to include the operation of the centrifuge and coverslipping of specimen slides. 3. During an interview on November 15, 2023 at 8:30 AM the Laboratory Director/Technical Supervisor confirmed these findings.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on the microscopic review of 113 negative non-gynecologic cytology cases from January 2021 to November 2023, the Technical Supervisor failed to verify the accuracy of 11 non-gynecologic cytology tests. 1. CY23-24 04/03/2023 Direct Smears and Cell Block Pancreas Mass Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Positive for Malignancy TECHNICAL SUPERVISOR DIAGNOSIS: Positive for Necrotic Malignant Cells 2. CY21-57 08/11/2021 Direct Smears and Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory due to Blood TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Bloody Smear 3. CY21-80 11/05/2021 Direct Smears and Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 4. CY21-95 12/09/2021 Direct Smears and

Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Scant Cellularity 5. CY21-98 12/09 /2021 Direct Smears and Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 6. CY22-11 02/14/2022 Direct Smears and Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Blood with Scant Inflammatory Cells 7. CY22-21 04/04/2022 Direct Smears and Cell Block Peritoneal Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Bloody TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Bloody 8. CY22-45 06/23/2022 Direct Smears and Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 9. CY23-17 03/17/2023 Direct Smears and Cell Block Peritoneal Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular 10. CY23-39 05 /24/2023 Direct Smears and Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Scant Cellularity 11. CY23-60 08/04/2023 Direct Smears and Cell Block Pleural Fluid LABORATORY DIAGNOSIS: Negative for Malignant Cells SURVEY TEAM DIAGNOSIS: Unsatisfactory Acellular TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory Acellular

D9999

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