

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0054055	<b>(X3) Date Survey Completed</b>  02/23/2023
<b>Name of Provider or Supplier</b>  Memorial Medical Center	<b>Street Address, City, State</b>  815 Virginia N Street, Port Lavaca, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable CLIA Conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D3025</b>	<p><b>REQUIREMENTS FOR TRANSFUSION SERVICES</b> CFR(s): 493.1103(d)</p> <p>Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, department of nurse's policy, reference books, and confirmed in interviews found the laboratory failed to ensure transfusion reaction policies promptly identified transfusion reactions for all blood products. The findings were: 1. An interview with surgical RN#1 on 2/23/2023 at 11:30 am at the nurse front desk that surgical RN#1 stated the blood pressure was three numbers on systolic and diastolic pressures ortwo numbers on systolic and diastolic pressures, and significant spike in temperatures will call the doctor for further instructions. 2. An interview with ER RN#1 on 2/23/2023 at 12:15 pm in the ER nurse station that ER RN#1 stated the blood pressure change was +/- 20 from the baseline, pulse change +/-</p>

10, and temperatures rises 2C would be call for transfusion reactions and stops the transfusion. 3. Review of the laboratory's policy titled INVESTIGATION OF POSSIBLE TRANSFUSION REACTIONS revealed "... In addition, if bacterial contamination is suspected (characterized by significant fever, {generally > and = 1C or 2F rise in temp}, shock, and disseminated intravascular coagulation (DIC) the trasfusion should be stopped immediately...." 4. Review of the department of nursing policy titled Blood Product Transfusion revealed "5. Review possible transfusion reaction symptoms: -Fever (often defined as > and = 1C or 2F above baseline), with or without cills -Shaking, chills, with/without fever -Pain at infusion (IV) site, chest, abdomen or flasnk -Blood pressure changes either hypertension or hypotension - Diffuculty breathing (painful or rapid) -Skin changes (flushing, itching, or swelling) - Nausea (with or without vomitting) -Rapid onset of infection (fever, chills) - Anaphylaxis -Urine color changes -Vision changes" "16. When a transfusion reaction is suspected the nurse must: -Stop the transfusion -Keep the IV open with 0.9 percent normal saline -Report the reaction to both the laboratory and attending physician immediately -Do clerical check at bedside of identifying the tags and numbers -Treat symptoms per physician's order and monitor vital signs -Send blood bag with attached administration set and labels along with the form "Investigation of Suspected Blood Transfusion Reaction" to the lab. -Collect blood abd urine samples and send to lab\* - Document thoroughly on transfusion reaction form and inpatient chart \*If bacterial contamination is suspected (characterized by significant fever, [generally > and = 2C or 4F above baseline rise in temp], shock, and disseminated intravascular coagulation (DIC) the trasfusion should be stopped immediately...." 5. Review of three references listed in the department of nursing policy revealed no documentation to identify transfusion reaction symptoms. The Lippincott Manual of Nursing Practice AABB Technical Manual, 13th Edition Transfusion Therapy Guidelines for Nurses (National Blood Resource Education Program) 6. Review of the transfusion traction policies for the laboratory and for the nursing revealed the laboratory had no documentation of transfusion reaction symptoms and policies from both departments did not match on rise in temperatures for suspected transfusion reaction. 7. An interview with the laboratory's technical supervisor and general supervisor on 2/23/2023 at 12:50 pm in the office confirmed the above findings. Key: RN=Registered nurse ER=Emergency room

**D5221**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:  
Based on review of the College of American Pathologists' (CAP) instructions for evaluating proficiency testing (PT) results, review of the laboratory's PT records for 2021 and 2022, and staff interview, it was determined the laboratory failed to document evaluation of "Not Graded" results for two of two 2022 LPX Laboratory Preparedness Exercise events as per PT agency's instructions. Findings included: 1. Review of the College of American Pathologists' instructions for evaluating PT results revealed: "The CAP uses exception reason codes that signify the proficiency testing (PT) for an analyte has not been graded. ...Your laboratory must identify all analytes with an exception reason code, review, and document the acceptability of performance as outlined below..." And, "Code: 26 ...Action required: Review participant summary for comparative results and document performance accordingly." 2. Review of the laboratory's PT records for 2021 and 2022 revealed the following

two of two 2022 LPX events for which the specimen results were graded with the exception code 26: CAP Event: LPX-A 2022 Sample: Grade: LPX-01 See Note [26] LPX-02 See Note [26] LPX-03 See Note [26] No evaluation and acceptability of performance for the event's samples was documented. CAP Event: LPX-B 2022 Sample: Grade: LPX-04 See Note [26] LPX-05 See Note [26] LPX-06 See Note [26] No evaluation and acceptability of performance for the event's samples was documented. 3. In an interview on 02/21/2023 at 1430 hours in the surgery waiting room, the laboratory's Technical Supervisor number one (as defined on submitted Form 209), after review of the data, confirmed the findings.

**D5393**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(b)(c)

The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, specimen logs, patient final reports, and confirmed in interview of laboratory personnel, the laboratory's preanalytic quality assurance plan failed to identify and correct errors when the laboratory receives specimens from outside locations for 9 of 40 patient samples from November 1, 2022 to December 31, 2022. The findings included: 1. Review of the laboratory's policy titled "Pre-analytic Policy" approved by the laboratory director on December 16, 2022, stated, "Scope: All Laboratories [sic] employees shall adhere to this Policy, which applies to all specimens/samples, including specimens on deceased individuals." and; "Pre-analytic Standard Operating Procedures: - Patient preparation, when applicable - Specimen/sample collection - Specimen/sample labeling, including patient name or unique patient/sample identifier and, when appropriate, specimen source, specimen date. - Specimen/sample storage and preservation - Specimen/sample transport conditions - Specimen/sample processing - Specimen/sample acceptability and rejection - Specimen/sample submission, handling and referral, and - Acceptance criteria specific to each assay - Required Acceptability Criteria for Specimen/Samples" and; "Specimens Brought Into the Lab - Important Information: The Lab Assistant/Lab Tech will check the temperature of all specimens with the temp gun and log them [sic] temp on the space provided on the specimen log in sheet. Lab Assistants need to keep up with temp gun expiration date and let Lab Manager know a month prior to expiration. - Acceptable Ranges: - Refrigerated/Cold Packs: 2 - 10 degrees Celsius - Room Temperature: 15 - 30 degrees Celsius - Frozen -20 degrees Celsius or colder" The policy went on to state, "Procedure for Rejection of Specimen /Sample: g. Specimen stability compromised (i.e. age of specimen, temperature stored, expired media/tubes, blood tubes received 2 hours or after, etc." 2. Review of patient specimen logs found the laboratory had an acceptable specimen transport range of 2-25 degrees Celsius. a. Review of the patient specimens logs found the following 9 of 40 samples reviewed from November 1, 2022 to December 31, 2022 had temperatures documented out of range or not documented: Patient Specimen Date & Time Agency Error Initials Received RG Urine 11-16-2022 @1129 BSL No temperature MP Urine 11-16-2022 @1129 BSL No temperature AB Urine 12-24-2022 @2346 BSL No temperature JR Blood/Urine 12-26-2022 @1304 BSL No temperature AC Urine 12-27-2022 @1746 CHH No temperature RW Blood 12-27-

2022 @0512 BSL No temperature GC Blood 12-29-2022 @1136 CHH No temperature NM Urine 12-29-2022 @1245 HH 29 EC Urine 12-30-2022 @1414 Hospice No temperature 3. Review of the patient reports for each of the 9 of 40 samples reviewed found each specimen result was finalized on the days they were received and had not been rejected due to either no temperature documented or temperature documented out of range. 4. The laboratory was asked to provide documentation that the laboratory followed its "Pre-Analytic Policy" to ensure specimens are transported at the appropriate temperature. No documentation was provided. 5. In an interview at 11:00 hours on 2/22/2022 in the laboratory, the Technical Consultant confirmed temperatures were not documented or were documented out of range.

**D5403**

PROCEDURE MANUAL  
CFR(s): 493.1251(b)

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 the laboratory's test menu, review of manufacturer's package inserts/instructions for use for urine drug screen (UDS) testing, review of laboratory's patient test logs for 2022 and staff interview it was determined the laboratory failed to have protocols in place to verify/check all urine samples for adulteration prior to UDS testing. Findings included: 1. Review of the laboratory's test menu revealed the laboratory performed UDS testing for the following drugs/drug derivatives: Amphetamine Ethyl Alcohol Barbiturate Benzodiazepine Cocaine metabolite Methadone Methaqualone Opiate Phencyclidine Propoxyphene Cannabinoid 2. Review of package inserts/instructions for use for the above drugs/drug derivatives' assays revealed: Beckman Coulter Emit II Plus Amphetamine Assay (August 2010; 9C052.5D\_C): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Ethyl Alcohol Assay (September 2013; 9K052.3D\_D): "SPECIMEN COLLECTION AND PREPARATION ... Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Barbiturate Assay (September 2013; 9D052.5D\_D): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If

adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Benzodiazepine Assay (September 2013; 9F052.4D\_F): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Cocaine metabolite Assay (September 2013; 9H052.5D\_C): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Methadone Assay (September 2010; 9E052.5D\_B): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Methaqualone Assay (September 2010; 9Q052.2D\_B): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Opiate Assay (September 2010; 9B052.6D\_D): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Phencyclidine Assay (September 2013; 9J052.4D\_D): "SPECIMEN COLLECTION AND PREPARATION ... Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Propoxyphene Assay (September 2013; 9G052.2D\_D): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." Beckman Coulter Emit II Plus Cannabinoid Assay (September 2010; 9N052.2D\_B): "SPECIMEN COLLECTION AND PREPARATION ...Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen." 3. Review of laboratory's patient test logs revealed the laboratory performed a total of 1,061 UDS tests in 2022. 4. In an interview on 02/22/2023 at 1435 hours in the surgery waiting room, the laboratory's Technical Supervisor number one (as defined on submitted Form 209) stated that the laboratory does not check all urine samples for adulteration. This confirmed the findings

**D5411**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:  
Based on review of the manufacturer package insert/instructions for use (IFU) for the Prostate Specific Antigen (PSA) test, review of random patient records from December of 2022 to February of 2023 and staff interview it was determined the laboratory failed to follow manufacturer instructions for intended use of testing PSA in men 50 years or older for 2 of 60 patients reviewed. Findings included: 1. Review of the manufacturer package insert/instructions for use (IFU) for the Beckman Coulter Access Immunoassay Systems Hybritech PSA (REF 37200; 2008; WB A37415C) test revealed: "Intended Use ... This device is intended for the measurement of serum PSA in conjunction with digital rectal examination (DRE) as an aid in detection of prostate cancer in men 50 years or older. ... This device is further indicated for the serial measurement of PSA to aid in the prognosis and management of patients with prostate

cancer." 2. Review of random patient records from December of 2022 to February of 2023 revealed the following 2 of 60 patient samples were tested outside the scope of manufacturer's intended use: Patient:63285 Age: 49 Tested: 01/10/2023 Result: 0.1 nanograms/milliliter (ng/ml) Diagnosis: Dysuria Patient: 32572 Age: 47 Tested: 02/15/2023 Result: 0.0 ng/ml Diagnosis: Encounter for general adult medical examination without abnormal findings 3. In an interview on 02/22/2023 at 1450 hours in the surgery waiting room, the laboratory's Technical Supervisor number one (as defined on submitted Form 209), after review of the data, confirmed the findings.

**D5449**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on the review of the laboratory's QC records in 2022, patient result logs, and confirmed in an interview found the laboratory failed to have documentation of two levels of qualitative QC to include a positive and a negative QC for 18 of 50 days reviewed for Medline MONO test Cassette Kit. The findings were: 1. Review of the laboratory's QC records in 2022 using Medline MONO test Cassette Kit revealed 18 of 50 days reviewed had no documentation of two levels of qualitative QC to include a positive and a negative QC 2/2/2022 2/7/2022 3/7/2022 4/8/2022 4/19/2022 6/2/2022 6/21/2022 6/28/2022 6/29/2022 7/15/2022 8/4/2022 8/30/2022 9/23/2022 10/27/2022 10/28/2022 11/28/2022 11/30/2022 12/27/2022 2. Review the patient result logs for the above dates revealed 18 patients had MONO testing performed. 2/2/2022 Patient account# 1514087 2/7/2022 Patient account# 1514423 3/7/2022 Patient account# 1517331 4/8/2022 Patient account# 1521010 4/19/2022 Patient account# 1522112 6/2/2022 Patient account# 1526716 6/21/2022 Patient account# 1528661 6/28/2022 Patient account# 1529418 6/29/2022 Patient account# 1529500 7/15/2022 Patient account# 1531194 8/4/2022 Patient account# 1533515 8/30/2022 Patient account# 1536223 9/23/2022 Patient account# 1538878 10/27/2022 Patient account# 1542574 10/28/2022 Patient account# 1542647 11/28/2022 Patient account# 1545788 11/30/2022 Patient account# 1546221 12/27/2022 Patient account# 1548986 3. An interview with the technical supervisor#1 on 2/22/2023 at 4:45 pm in the surgical waiting room confirmed the above findings. Key: QC=Quality Control MONO-Infectious mono

**D5477**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
 Based on the review of the laboratory's policy, the manufacturer's packing slips, Media Quality Control logs June 2022 to January 2023, CMS 116 application, and confirmed in an interview found the laboratory failed to have documentation of sterility check and inspection of media upon receipt for 1 of 5 batches reviewed. The findings were: 1. Review of the laboratory's policy titled MEDIA QUALITY CONTROL AND QUALITY ASSURANCE under III METHOD revealed "C. Media will be inspected for 1. Cracked petri dish 2. Unequal filling of plates 3. Cracked medium in plates 4. Hemolysis 5. Freezing 6. Excessive number of bubbles 7. Contamination" 2. Review of the manufacturer's packing slips revealed the following, "QC Certification .... Inspect all culture media upon receipt following your internal quality control procedures." 3. Review of the manufacturer's packing slips revealed 16 types of microbiological media were received on 11/1/2022. Anaerobic (CDC) LKV Blood Agar Anaerobic (CDC) PEA Blood Agar Blood Agar, 5% sheep blood Chocolate Agar Columbia CAN w/5% sheep blood MacConkey Agar MacConkey w/Sorbitol MH Agar (100mm) Salmonella Shigella Agar TCBS Agar Thayer Martin, modified Yersinia Sel (CIN) Agar Blood/MacConkey Biplate Blood Agar, 5% sheep blood (slant) Spectra MRSA SLD Agar 4. Further review of the manufacturer's packing slips revealed no documentation of inspection for the batch of media received on 11/1/2022. 5. Review of the Media Quality Control log revealed no sterility check for the 16 types of media above received on 11/1/2022. 6. Review of the laboratory's CMS 116 application signed by the laboratory director on 2/15/2023 revealed the annual volume for Microbiology was 12, 596. 7. An interview with the general supervisor and the testing personnel#11 on 2/22/2023 at 12:05 pm in the microbiology lab confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's plan of correction for survey completed on 07/21/2021, review of the laboratory's corrective action records for June of 2022 to January of 2023, review of laboratory's Quality Assurance (QA) records for the same interval and staff interview it was determined the laboratory's QA failed to document review/evaluation of effectiveness of corrective action for plasma separation from cells within 15 minutes from collection for lactic acid testing. Findings included: 1. Review of the laboratory's plan of correction (signed by laboratory director on 07/30/2021) for survey completed on 07/21/2021 revealed: "THE TS, GS, OR TP WILL REVIEW THE PLASMA IS BEING SEPARATED WITHIN 15 MINUTES ROUTINELY. ... THE GS LEFT A COPY OF THE LACTIC ACID PACKAGE INSERT FOR ALL T. P. TO SIGN." Legend: TS = Technical Supervisor GS = General Supervisor TP/T.P. = Testing Person 2. Review of the laboratory's corrective action records for June of 2022 to January of 2023 revealed the following corrective actions were taken for patient samples exceeding 15 minutes limitation for separation of plasma from cells

for testing of lactic acid: Patient: 1527814 Time collected: 06/13/2022 at 1553 Time Received: 06/13/2022 at 1608 Elapsed time: 15 minutes Corrective action: Investigation; Staff counseling/documentation Patient: 1528862 Time collected: 06/22/2022 at 1915 Time Received: 06/22/2022 at 1943 Elapsed time: 30 minutes Corrective action: Investigation; Staff counseling/documentation Patient: 1534691 Time collected: 08/16/2022 at 1609 Time Received: 08/16/2022 at 1656 Elapsed time: 47 minutes Corrective action: Investigation; Staff counseling/documentation Patient: 1547446 Time collected: 12/12/2022 at 0630 Time Received: 12/12/2022 at 0655 Elapsed time: 25 minutes Corrective action: Investigation; Staff counseling /documentation Patient: 1548228 Time collected: 12/17/2022 at 1315 Time Received: 12/17/2022 at 130 Elapsed time: 25 minutes Corrective action: Investigation; Staff counseling/documentation Patient: 1550784 Time collected: 01/12/2023 at 0836 Time Received: 01/12/2023 at 0857 Elapsed time: 21 minutes Corrective action: Investigation; Staff counseling/documentation

3. Review of laboratory's Quality Assurance (QA) records for the same interval revealed there was no documentation of review/evaluation of effectiveness of the corrective action for the ongoing issue of plasma separation from cells beyond the required 15 minutes from collection for testing of lactic acid, or discussion of further actions to be taken to resolve the problem.

4. In an interview on 02/22/2023 at 1350 hours in the surgery waiting room, the laboratory's Technical Supervisor number one (as defined on submitted Form 209), after review of the data, confirmed the findings.

**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's specimen receipt logs, patient records, manufacturer instructions for use, quality assurance (QA) records and staff interview it was determined the Laboratory Director failed to ensure laboratory's QA identified and corrected quality failures as they occurred. Refer to D5393 and D5793.