Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0391053	04/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Milwaukee Health Service Systems, Llc	4800 S 10th St, Unit 1, Milwaukee, WI	

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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: The facility was not in compliance with Wisconsin Administrative Code (Wisc. Admin. Code) based on citations noted by the Wisconsin Department of Health Services (DHS) Behavioral Health Certification Section (BHCS) on April 27, 2020. Findings include: 1. Milwaukee Health Service Systems did not comply with the Wisc. Admin.Code ch. DHS 75, Community Substance Abuse Service Standards, based on survey results from April 16, 2020. BHCS cited deficiencies at X1308, X1671, X1697, and X1725 for provider number 1644 on the Wisconsin State 2567.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on surveyor review of laboratory documents, video conference observation of access to and storage of urine specimens, and video conference and telephone interviews with testing personnel, video conference and telephone interview and email correspondence with the regional director, and email correspondence with the laboratory director, the laboratory did not meet the requirements specified in 493.1231 through 493.1252 and 493.1291 through 493.1299. Findings include: 1. Access was

	not restricted to the storage area where urine specimens are stored before and after testing, and the laboratory has not ensured confidentiality of patient information. See D5201. 2. The laboratory did not follow their written procedures or meet the manufacturer's requirements to ensure optimum integrity of patient specimens. See D5203. 3. The laboratory did not have a system to document all complaints and problems reported to the laboratory. See D5205. 4. The procedure manual did not include step-by-step instructions for responding to analyzer flags, and did not define the specific control materials used for each test performed. See D5403. 5. The laboratory director did not approve, sign, and date the manufacturer instructions used as testing procedures. See D5407. 6. The laboratory did not monitor or document the temperature of the unrefrigerated storage area where the laboratory kept urine specimens prior to testing. See D5413. 7. The cut off value for fentanyl was not consistent between the laboratory procedures, manufacturer's instructions, and the test report. See D5805. 8. The test reports for specimens received from six of the seven facilities in West Virginia did not indicate the testing laboratory's name. See D5805. 9. The test report did not include information necessary for the interpretation of test results. See D5805. 10. The laboratory did not define in writing their time frames for reporting patient results and did not consider the urgency of the tests requested in establishing reporting time frames. See D5815. 11. The laboratory had not monitored, assessed, or corrected problems with turnaround time for reporting patient test results. See D5891.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on surveyor video conference observation of access to the storage area and the storage area, and interview via video conference with the regional director, access to the area where the laboratory stores urine specimens was not restricted and the laboratory had not ensured confidentiality of patient information. Findings include: 1. Video conference observation of access to the storage area on April 16, 2020 at 9:50 AM revealed two unlocked doors between the storage area and the clinic and laboratory areas of the facility. 2. Video conference observation of the storage area on April 16, 2020 at 9:55 AM revealed the area housed four double-doored refrigerators. Observation of the contents of the refrigerators showed all four filled with specimens from multiple facilities in Wisconsin and West Virginia; the specimen labels included patient information. Further observation revealed more than ten boxes on the floor, each box containing 24 or more urine specimens labeled with patient information. 3. Video conference observation of the hallway door and the door to the storage area on April 16, 2020 at 10:42 AM revealed neither door had locks and did not restrict access to the storage area. 4. Video conference interview with the regional director, staff A, on April 16, 2020 at 10:42 AM confirmed access to the storage area containing patient urine specimens with patient information was not restricted and the laboratory did not ensure confidentiality of patient information.
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 surveyor video conference observation of storage of untested urine specimens, review of laboratory procedures, manufacturer's instructions, temperature logs, and laboratory reports, video conference interview with testing personnel, and video conference and telephone interview with the regional director, the laboratory has not followed their written procedures and manufacturer's requirements to ensure optimum integrity of thousands of patient specimens since February 2020. Findings include: 1. Video conference interview with the regional director on April 16, 2020 at 10:10 AM revealed the laboratory kept urine samples refrigerated until the laboratory personnel take them to the laboratory for testing. At 10:30 AM, the regional director stated there was no other storage area other than the area the director displayed. 2. Observation of a second aisle of storage by video conference on April 16, 2020 at 12: 20 PM revealed three large shelves and multiple mailboxes on the floor holding delivery boxes and bags. Review of the packages revealed the laboratory received the shipments from April 7 through April 15, 2020. The delivery labels on the packages showed the laboratory received at least 26 of the packages from April 7 through 10, 2020. A representative package from Appleton, Wisconsin contained about 25 samples collected on April 3, 2020, shipped on April 8, 2020, and received on April 10, 2020. Further observation revealed a thermometer at the end of the shelves near the specimens. The thermometer showed the temperature was 62 degrees Fahrenheit (F). 3. Interview via video conference with testing personnel, staff B, on April 16, 2020 at 12:35 PM confirmed the laboratory routinely stored urine specimens on the shelves since February 2020 when staff B was hired. The interview also confirmed the laboratory did not monitor the temperature of the storage area. 4. The laboratory procedure "SOP 1 Daily Laboratory Start-up Functions" includes the following instructions: "7. Urine specimens not processed on date received are to be refrigerated until processing occurs." 5. Review of the manufacturer's instructions for the DRI Ethyl Glucuronide test performed in the laboratory showed, "Urine samples must be stored refrigerated at all times when not in use." 6. Review of the laboratory's temperature monitoring logs showed the acceptable temperature range for refrigerator storage is 36 - 46 F. 7. Review of collection reports listing the specimens collected from April 7 through April 15, 2020 at 19 facilities that refer specimens to this laboratory showed 6,953 specimens collected from the following locations: Location / Number of specimens Appleton /457 Beckley / 277 Beloit / 333 Charleston / 405 Clarksburg / 162 Green Bay / 646 Huntington / 488 Madison East / 657 Madison West / 271 North West / 378 Parkersburg / 145 Racine / 309 Rivers Shore / 389 Sheboygan / 313 Waukesha / 282 Wausau / 448 West Milwaukee / 590 Wheeling / 156 Williamson / 247 8. Interview via video conference with the regional director, staff A, on April 16, 2020 at 12:24 PM confirmed urine specimens collected between April 3 and April 15, 2020 were stored on shelves in an unmonitored area that was not environmentally controlled. Further interview confirmed staff moved samples from the shelves to the refrigerators on April 10, 2020. The director stated there were no records to show what samples staff moved or how long they had been stored without refrigeration before the transfer to refrigerated storage. Interview via telephone on April 17, 2020 at 12:30 PM confirmed the laboratory had not tested most of the samples identified on the collection lists.
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 surveyor telephone interview with testing personnel and email correspondence with the regional director, the laboratory did not have a system to document all complaints and problems reported to the laboratory. Findings include: 1. Telephone interview on April 18, 2020 at 10:00 AM with testing personnel, staff B, revealed the laboratory received complaints and concerns by telephone and email. Staff B stated they were not aware of any system to document complaints other than those received via email and further stated the email system deletes emails after one month. 2. Email correspondence with the regional director, staff A, on April 20, 2020 at 5:16 PM confirmed the laboratory did not have a system for documenting complaints reported to the laboratory.
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 surveyor review of the laboratory procedure manual and email communication with the laboratory director, the laboratory procedures did not provide step-by-step instructions for approving results and did not identify the specific control materials required for each analyte. Findings include: 1. Review of the "Policy and Procedure Manual" showed "SOP 11 Approving Results and Printing Reports on Paracelsus" includes the following instructions, "Scan over results to verify results have acceptable outcomes and no "R" results". The procedure did not identify what an "R" result is or what steps to take to resolve the issue. 2. Review of the "Policy and Procedure Manual" showed "SOP 4 Immunoassay Drug Screening Procedure" included a table identifying the controls for each analyte. The table directed use of two levels of controls for each analyte (low and high) but did not specify the control

	material needed. Further review of the manual showed no other identification of the specific control materials needed. 3. In an email communication on April 23, 2020 at 3:29 PM, the laboratory director confirmed SOP 4 and 11 needed updating.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the procedure manual and manufacturer's instructions, and email correspondence with the regional director, the laboratory's procedures for the individual analytes tested in the laboratory were not individually approved, signed, and dated by the laboratory director and were not included in the table of contents as part of the procedure manual. Findings include: 1. Review of the "Laboratory Policy and Procedure Manual" table of contents showed no indication procedures for each individual analyte were included in the manual. 2. Review of the manufacturer's instructions for six analytes (Methadone, Methadone metabolites, Fentanyl, Opiate, Oxycodone, Ethyl Glucuronide, and Creatinine) showed no evidence of approval by the laboratory director. 3. Email correspondence from the regional director, staff A, on April 17, 2020 at 8:00 PM stated the manufacturer's instructions were with the procedure manual. This is a repeat deficiency previously cited on November 11, 2011.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation of the storage area via video conference, review of laboratory temperature monitoring records, and video conference and telephone interview with testing personnel and video conference interview with the regional director, the laboratory did not monitor or document the temperature of the unrefrigerated storage area where the laboratory stored delivered packages of urine specimens prior to testing. Findings include: 1. Video conference observation of the storage area on April 16, 2020 at 12:25 PM revealed three full shelves holding delivered packages of urine specimens and additional packages in mailboxes on the floor. A thermometer at the end of the shelf showed the temperature in the area was 62 degrees Fahrenheit. 2. Review of laboratory temperature monitoring records showed no evidence of documented temperature monitoring in the unrefrigerated storage area. 3. Interview with testing personnel, staff B, on April 16, 2020 at 12:35 PM via video conference confirmed laboratory staff did not monitor or document the temperatures in the storage area. During a telephone interview on April 18, 2020 at 10: 00 AM, staff B stated the laboratory personnel did not document when personnel

	moved samples from unrefrigerated to refrigerated storage. 4. Interview with the regional director, staff A, via video conference on April 16, 2020 at 9:54 AM confirmed the storage area was not temperature controlled.
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: Item 1: Based on surveyor review of patient test reports, manufacturer instructions, and the laboratory's test menu, and email correspondence with the regional director, the cut-off used for the Fentanyl assay on the patient report is not consistent with the information in the test menu and the manufacturer's instructions. Findings include: 1. Review of patient test reports showed the cutoff for Fentanyl is greater than or equal to 100%. 2. The manufacturer's instructions stated, "The 2.0 ng/mL calibrator is used as a cutoff reference for distinguishing 'positive' from 'negative' samples". (ng/mL: nanograms per milliliter) 3. The "Test Menu" in the laboratory's procedure manual showed the reference range for Fentanyl is less than two. 4. In an email on April 23, 2020 at 2:09 PM, the regional director, staff A, provided the following response from their vendor, "When it was developed and validated in-house at Thermo Fisher, they chose to normalize that assay at 100% due to its low cutoff concentration of 2 ng/mL. Since it is normalized at 100%, any result less than 100 is negative and any result over 100 is positive." The regional director provided no further explanation of the difference between the manufacturer's instructions, the test menu, and the test report. Item 2: Based on surveyor review of patient test reports and email correspondence with the regional director, the test report did not indicate the name of the testing laboratory for samples originating from six of seven locations in West Virginia. Findings include: 1. Review of patient test reports from six of the seven locations in West Virginia that sent samples to this laboratory for testing showed no indication of the name of the laboratory performing the testing. The name on the header of the report showed the city name followed by "Treatment Center Urine Drug Screen Report". The "Milwaukee Health Service Systems" laboratory name was not on the reports for specimens received from Beckley, Charleston, Huntington, Parkersburg, Wheeling, or Williamson. 2. Email correspondence with the regional director, staff A, on April 27, 2020 at 11:23 AM confirmed the name of the testing laboratory was not included on the report. Item 3: Based on surveyor review of manufacturer's instructions and patient test reports, and email correspondence with the regional director, the test report did not include information necessary for interpretation of the test results. Findings include: 1. Review of manufacturer's instructions for the DRI Methadone, DRI Opiate, DRI Oxycodone, DRI Methadone Metabolite, DRI Fentanyl, and DRI Ethyl Glucuronide assays showed each includes a statement similar to the following: "The assay provides only a preliminary analytical test result. A more specific alternative method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GS/MS) and is the preferred

	confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used." 2. Review of patient test reports showed no indication the results are only preliminary analytic results. 3. Email correspondence with the regional director, staff A, on April 27, 2020 at 10:23 AM confirmed the laboratory report did not include the interpretive information and the laboratory did not provide the information to clients. This is a repeat deficiency previously cited on December 8, 2015.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on surveyor review of procedures, test reports and records, and video conference interview and email correspondence with the regional director, the laboratory did not define their time frames for reporting patient results and did not consider the urgency of the tests requested in establishing their reporting time frames. Findings include: 1. Video conference interview with the regional director, staff A, on April 16, 2020 at 9:40 AM revealed the expected time frame for reporting patient results was seven to ten days. 2. In email correspondence on April 23, 2020 at 3:30 PM, staff A stated, "Our lab turn around is up to 30 days as we have up to 30 days from collection to test it." 3. Review of specimen testing records showed on April 7, 2020 the laboratory tested specimens collected on March 17, 2020 (21 days after collection). Records from testing performed on April 8, 2020 showed the laboratory tested specimens collected on March 19, 2020 (20 days after collection). 4. Review of patient test reports showed the following patients receiving narcotic treatment service at 10th Street Clinic had subsequent specimens collected before the laboratory had tested the previously collected specimen. Client 1 (first name on reports was incorrectly spelled) Collected 02/04/2020; tested 02/21/2020 + cannabinoid, cocaine, and buprenorphine Collected 02/17/2020; tested 03/03/2020 + cannabinoid and buprenorphine Collected 02/28/2020; tested 03/13/2020 + cannabinoid and buprenorphine Collected 03/12/2020; tested 03/17/2020 + cannabinoid, opiate, and buprenorphine Client 3 Collected 02/03/2020; tested 02/18/2020 + opiate and EDDP Collected 02/10/2020; tested 02/26/2020 + opiate and methadone Collected 02/20 /2020; tested 03/09/2020 + opiate and methadone Collected 03/04/2020; tested 03/17 /2020 + fentanyl, EDDP and opiate Collected 03/12/2020; tested 03/17/2020 + opiate and methadone Client 4 Collected 02/25/2020; tested 03/09/2020 + cocaine and methadone Collected 03/05/2020; tested 03/17/2020 + cocaine and EDDP Collected 03/09/2020; tested 03/20/2020 + cocaine and EDDP Collected 03/17/2020; tested 03 /21/2020 + cocaine and methadone 5. Review of laboratory procedures showed no evidence the laboratory defined established time frames for testing and reporting test results that ensured providers who received the results could effectively use the results in evaluating and treating patients.
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 surveyor review of quality assurance records, observation of specimens in the laboratory, interview via video conference and telephone with testing personnel, and video conference interview and email communication with the regional director, the laboratory has not monitored, assessed, or corrected problems with turnaround time for reporting patient test results. Findings include: 1. Video conference interview with the regional director, staff A, on April 16, 2020 at 9:40 AM revealed the expected turnaround time for patient test results was seven to ten days. Staff A also stated the laboratory's turnaround was currently two weeks. 2. Video conference observation of specimens in the laboratory and interview with testing personnel, staff E, on April 16, 2020 at 9:40 AM revealed the laboratory was testing specimens collected on March 30, 2020 and received on April 1, 2020 (17 days after collection). 3. Email communication from the regional director to client facilities showed that as of March 31, 2020 the laboratory had completed testing through: Date / number of clinics (number of days to report) March 12 / 1 clinic (19 days) March 13 / 1 clinic (18 days) March 14 / 1 clinic (17 days) March 16 / 11 clinics (15 days) March 17 / 4 clinics (14 days) March 24 / 1 clinic (7 days) March 30 / 1 clinic (1 day) 4. Telephone interview with testing personnel, staff B, on April 18, 2020 at 10:00 AM revealed the laboratory has had 6,000 to 10,000 untested specimens each day since February 2020. 5. Review of quality assurance records provided by the regional director, staff A, showed no documented monitoring of turnaround time or any documented corrective actions put in place to address delays in patient test result reporting. 6. Email correspondence from the regional director, staff A, on April 27, 2020 at 10:23 AM provided a list of quality indicators in the laboratory; the list did not include any post-analytic measures.
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 surveyor review of laboratory records, procedures, manufacturer's instructions and verification studies, observation of untested specimens via video conference, video conference and telephone interviews with testing personnel, and video conference interview with the regional director, the laboratory director did not meet the requirements of 493.1445 of this subpart. Findings include: 1. The laboratory director did not ensure the laboratory employed sufficient staff to promptly perform and report test procedures. See D6079. 2. The laboratory director did not ensure sufficient refrigerated space was available to store untested specimens as required in the manufacturer's instructions and laboratory procedures. See D6083. 3. The laboratory director did not ensure the Ethyl Glucuronide verification procedures were adequate to ensure the use of unrefrigerated specimens did not negatively affect the performance of the test system. See D6086.
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 surveyor review of laboratory records, observation of untested specimens via video conference, video conference interview with testing personnel and the regional director, and telephone interview with testing personnel, the laboratory director did not ensure the laboratory employed sufficient staff to promptly perform and report test procedures. Findings include: 1. Video conference observation on April 16, 2020 at 12:25 PM revealed untested patient specimens stored on three shelves, in boxes on the floor, and in four refrigerators in the storage area. Dates on the delivery packages showed the laboratory received the packages from April 1 through April 15, 2020. 2. Video conference observation and interview with testing personnel in the laboratory, staff E, via video conference on April 16, 2020 at 9:40 AM revealed the laboratory was testing samples collected on March 30, 2020. 3. Review of an excel spreadsheet of all specimens tested on April 7, 2020 showed 876 specimens from March 17 to March 23, 2020 were tested. Review of a similar spreadsheet for April 8, 2020 showed the laboratory tested 451 specimens from March 19 through March 24 and April 3 through April 8, 2020. 4. Interview with the regional director, staff A, on April 16, 2020 via video conference at 9:40 AM revealed the expected turnaround time for specimens was 7 - 10 days. Further interview confirmed the laboratory was currently testing samples collected on March 30, 2020 and that the laboratory received about 1000 specimens each day. 5. Interview with testing personnel, staff B, via telephone on April 18, 2020 at 10:00 AM revealed the backlog each day has varied from 6,000 to 10,000 specimens since February 2020. Further interview revealed testing personnel were performing some of the general supervisor's tasks and had less time to perform testing. 6. During a telephone interview with testing personnel, staff G, on April 18, 2020 at 10:30 AM, staff G stated the backlog fluctuates, but had been consistently over 6000 each day. Staff G also stated the addition of work from West Virginia had doubled the amount of testing and that administration overestimated the capacity of the laboratory.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and manufacturer's instructions, video conference observation of the storage of untested urine specimens and video conference interview with the regional director, the laboratory director did not ensure

	sufficient refrigerated space was available to store untested specimens according to the laboratory's procedures and manufacturer's instructions. Findings include: 1. The laboratory procedure, "SOP 1 Daily Laboratory Start-up Functions" stated, "7. Urine specimens not processed on date received are to be refrigerated until processing occurs." 2. The DRI Ethyl Glucuronide manufacturer's instructions stated, "Urine samples must be stored refrigerated at all times when not in use." 3. Video conference observation of untested urine specimens in the storage area on April 16, 2020 at 12:25 PM revealed three shelves and several mailboxes on the floor filled with delivery packages dated from April 8, 2020 through April 15, 2020 containing untested urine specimens. A thermometer on the shelf showed the temperature in the unrefrigerated area was 62 degrees Fahrenheit. Four double-doored refrigerators were also full of both untested and tested specimens. 4. Video conference interview with the regional director, staff A, on April 16, 2020 at 12:30 PM revealed the laboratory received about 1000 specimens a day and confirmed there was not enough refrigerated storage space to store all the specimens prior to testing.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of manufacturer's instructions, observation of the specimen storage area, and verification studies performed for Ethyl Glucuronide, the laboratory director did not ensure the Ethyl Glucuronide verification procedures were adequate to ensure the use of unrefrigerated specimens did not negatively affect the performance of the test system. Findings include: 1. Review of the manufacturer's instructions showed the DRI Ethyl Glucuronide test requires refrigeration of the urine specimens at all times prior to processing. 2. Observation of the storage area by video conference on April 16, 2020 at 12:25 PM showed specimens were stored unrefrigerated prior to testing. 3. Review of the verification evaluations performed by the laboratory showed no indication the laboratory evaluated the impact of unrefrigerated storage on the specimens tested for Ethyl Glucuronide.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory Personnel Report, video conference interview with the regional director, and telephone interviews with testing personnel, the laboratory did not have a qualified general supervisor providing day-to-day oversight for testing personnel for the past six weeks. Findings include: 1. The laboratory did not have a general supervisor providing day-to-day oversight of the laboratory's operation and personnel performing high complexity toxicology testing for the six weeks prior to the survey. See D6142.

D6142	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Personnel Report, video conference interview with the regional director, and telephone interviews with testing personnel, the laboratory did not have a general supervisor providing day-to-day oversight of the laboratory operation and personnel performing high complexity toxicology testing for the six weeks prior to the survey. Findings include: 1. Review of the CMS (Centers for Medicare and Medicaid Services) Form 209 Laboratory Personnel Report showed staff F identified as the only general supervisor for the laboratory. 2. Interview with the regional director, staff A, via video conference on April 16, 2020 at 12:50 PM revealed staff F was on leave for the past six weeks. Further interview revealed two of the four testing personnel started in the laboratory in the last two days; the other two testing personnel had started in February 2020. 3. During a telephone interview on April 18, 2020 at 10:30 AM with testing personnel, staff G stated the general supervisor tasks had been split between staff A, staff D, and the laboratory staff. 4. During a telephone interview on April 18, 2020 at 10:00 AM, testing personnel, staff B, stated there was no official supervisor. Staff B stated testing personnel were informed staff A would be the acting supervisor and testing personnel would be responsible for some of the general supervisor's work during the supervisor's leave. Staff B also stated staff A was not on site initially after the general supervisor went on leave and was not providing the day-to-day supervision that staff F provided.