Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0642180	09/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dewitt Hospital And Nursing Home	1641 South Whitehead Drive, De Witt, AR	

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
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: Through review of the manuafactuer's package insert for Lactic Acid reagent, laboratory chemistry policy and procedure manual, lack of documentation and interview it was determined that the laboratory failed to have a policy and procedure for the collection and handling of specimens and performance of Lactic Acid Assays. This would affect all lactic acid assays performed. Findings follow: A) Review of the manufactuer's package insert for the performance of lactic acid on the Demension EXL 200 analyzer revealed that specimens should be drawn without the use of a tourniquet using a tube with NaFl preservative, immediately placed on ice, separated

	from cells within 15 minutes, performed immediately or frozen. B) In an interview on 9/16/20 at approximately 01:00 PM, the testing personnel identified as number three on the CMS 209 form stated that the plasma should be separated from cells within three hours and could not articulate the special handling requirements for lactic acid testing. C) Review of the chemistry policy and procedure manual under the tab for lactic acid revealed the procedure validation information but no procedure for performing the test or specimen handling requirements. D) Upon request on 9/16/20 at approximately 01:30 PM, the laboratory staff member identified as number four on the CMS 209 form, could not produce a policy and procedure for lactic acid testing and confirmed that there was no policy and procedure for lactic acid testing.
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: 35659 Through review of the manufacturer's package insert, review of documentation of the laboratory establishment of the normal patient mean value (MNPT), the CLSI document H47-A it was determined that the laboratory failed to establish the (MNPT) used in the calculation of International Normalized Ratio (INR) in accordance with test manufacturer instructions. Findings follow: A) Review of the manufacturer's package insert for Dade Innovin revealed that "for US customers the appropriate CLSI guidelines are recommended" in establishing the MNPT. B) The CLSI document H47-A states that an equal number of males and females spanning the age range of patients should be used to establish the MNPT. C) Review of the laboratory's data used in the establishment of the MNPT for Dade Innovin lot # 556992 lists 20 PT values without any patient demographics. D) Upon request, the laboratory staff member, identified as number five on the CMS 209 report, could not specify the gender or age of any of the normal patients used to establish the MNPT. E) In an interview on 9/15/20 at approximately 01:30 PM, the laboratory staff member, identified as number five on the CMS 209 form, confirmed that patient volunteers used to establish the MNPT were not identified by gender or age.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Through observation, review of the manufacturer's package insert and interview it was determined that the laboratory had not properly labeled one of one cartons of IL Control 9 - Multiqual with the correct expiration date. Findings follow: A) In a tour of the laboratory on 9/16/20 at approximately 01:30 PM, one of one carton of IL Control

	9 - Multiqual quality control material lot # 946 with an expiration date of 8/31/22 was observed at room temperature labeled "open 9/8/2020 expires 8/31/2022. B) Review of the manufacturer's package insert for IL Control 9 - Multiqual revealed " stable as shown on expiration date when stored at 2-8 degrees C. or up to 12 months at room temperature". C) In an interview on 9/16/20 at approximately 1:30 PM, the laboratory staff member identified as number eleven on the CMS 209 form confirmed that the material, identified above, was mislabeled and the expiration date should have been amended to 9/8/21.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory as well as interviews with laboratory staff, it was determined the laboratory had Urine/Cerebrospinal Fluid Protein reagents and calibrators available for use when they had exceeded their expiration dates. Survey findings include: A. During a tour of the laboratory, conducted at 10:56 on 9/15/2020, the surveyor observed 1 box of Dimension Flex Reagent Cartridge UCFP (Urine Cerebrospinal Fluid Protein) Lot # BC0233 that expired 8/20/2020 and Dimension Flex UCFP Calibrator Lot #aJD044 that expired 9/1 /2020. B. During an interview at the time of the tour, Employee #11 confirmed the Dimension Flex Reagent UCFP Cartridge and Dimension Flex UCFP Calibrator were available for use when they had exceeded their expiration. C. Use of expired chemistry cartridges and calibrators has the potential to affect all chemistry tests performed on the Dimension EXL chemistry analyzer. The laboratory reported an annual test volume of 33,685 chemistry tests performed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Through a review of new instrument verification documentation for the Sysmex XN 550 Hematology Analyzer, lack of documentation and interviews with laboratory staff, it was determined the laboratory failed to demonstrate that the Sysmex XN 550 Hematology Analyzer could obtain accuracy and precision established by the manufacturer: Survey Findings Follow: A. A review of the verification documentation for Sysmex XN 550 Hematology analyzer revealed that no data was present for verifying the accuracy and precision of the Hematology analyzer. B. Upon request, the laboratory was unable to provide documentation that the accuracy and precision of

	Sysmex Hematology analyzer installed on 6/29/2020 had been performed. C. In an interview at 14:00 on 09/15/2020, the technical consultant confirmed the laboratory could not produce documentation of verifying the accuracy and precision of the Sysmex XN 550 Hematology Analyzer.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Through observations made during a tour of the laboratory, a review of the Dimension EXL Daily System Checks for 2020, a review of the Patient Demographics reports for 7/26/2020 and 7/30/2020, and interviews with laboratory staff, it was determined the laboratory failed to perform and document daily system checks for the Dimension EXL on two days of testing. Survey findings include: A. During a tour of the the laboratory on 9/15/2020 at 10:10 a.m. the surveyor observed the Dimension EXL 200 as the only chemistry analyzer for all routine chemistry testing. B. The Dimension EXL Daily System Checks require documentation of the 293 Filter, Reagent 1 Mean and SD, Reagent 2 Mean and SD, Sampler Mean and SD, HM Mean and SD, LOCI Highest Value, CHK Lot, and Operator Initials. C. On 7/25/2020 and 7/30/2020 (two of thirty-one days in July 2020) the laboratory failed to document any of the required Dimension EXL Daily System Checks. D. The Patient Demographics reports for 7/26 /2020 revealed four patients (accession #200726009, #200726012, #200726015, and #200726017) had routine chemistry tests performed on the Dimension EXL and reports for 7/30/2020 revealed fifteen patients (Accession #20073017, #200730018, #200730019, #200730021, #200730022, #200730030, #200730033, #200730034, #200730035, #200730038, #200730040, #200730041, #200730042, #200730043, #and 200730044) had tests performed on the Dimension EXL when the system checks were not documented. Failure to perform Dimension EXL Daily System Checks had the potential to affect nineteen of nineteen patients tested on 7/26/2020 and 7/30/2020
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by:

	. Through a review of Hematology policy and procedure manual, Hematology Quality Control (QC) records for November 2019, March and July of 2020, laboratory patient log, lack of documentation as well as interview with staff it was determined the laboratory failed to document Hematology quality control when patients were tested. As evidenced by: A. A review of the Hematology policy manual revealed the Quality Control policy:"Three levels of Hematology controls will be tested each 12 hours of patient testing. 2 of the 3 controls should be within acceptable limits. Reject the run if QC exceeds the established ranges. Patient testing must be considered invalid if controls values are not within the expected limits." B. A review of QC data for the month of November of 2019 (one of twelve months reviewed), July and August of 2020 (2 of 9 months reviewed) revealed on the following days in July 2020 (July 21-July 22) the laboratory had no documentation of acceptable Quality Control for Hematology. C. A review of laboratory patient log revealed on July 21, 2020, the following patients had Complete Blood Counts reported: patient #34059, patient #31050, patient# 25023, patient #17536, patient #16545, patient #129292, patient #129293, patient #12634, patient #16545, patient #12135, patient #7166, patient #45485, patient #12917, patient #3211, patient #8302, patient #33801, patient #14808, patient #12530 and patient #128607: On July 22, 2020, the following patients had Complete Blood Counts reported: patient #9529, patient #15098, patient #36134, patient #12976, patient #12471, patient #4907 and patient #32508. D. In an interview on 9/16/2020 at 10:30, the technical consultant confirmed patients were tested and reported without acceptable QC for July 21-22, 2020.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the package inserts for BioRad Multiqual and BioRad Cardiac quality controls, a review of the laboratory quality control policy, a review of the "Laboratory Issue, Concern, Complaint Forms" for 2020, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to establish statistical parameters for chemistry quality control. Survey findings include: A. BioRad Multiqual and Liquichek Cardiac Markers Plus Control instructions for use state, "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." B. The laboratory quality control policy states, "Run parallel with each new lot of controls. When establishing a new range for unassayed control material - obtain data for a minimum of 1 month. Calculate mean X2 SD." C. The "Laboratory Issue, Concern, Complaint Form" dated 5/2/2020 states that the laboratory Cardiac Quality Control expired and the laboratory had no

	replacements. The new lot of Liquichek Cardiac Markers Plus Control (borrowed from another laboratory on 5/2/2020) was put into use on 5/2/2020. D. The "Laboratory Issue, Concern, Complaint Form" dated 8/14/2020 states that the laboratory ran out of Multiqual 3 for Chemistry Controls and borrowed some from another hospital. It also states the "exceptable ranges" varied from previous lot #. E. There was no documentation of establishment of ranges through parallel testing with previous lot of controls. F. In an interview, at 1:13 p.m.on 9/15/2020, employee #5 (as listed on the form CMS-209) confirmed that the laboratory failed to establish quality control ranges for the borrowed quality control and stated that the laboratory used package insert ranges as the acceptable range.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through review of Levy-Jennings QC charts for chemistry testing for January 2020, patient result reports, and interview it was determined that patient testing was performed and reported in three (3) of nine (9) instances when QC was unacceptable. Findings follow: A) Review of Levy-Jennings QC chart revealed that level 3 QC lot# 45793 for Lipase was unacceptable greater than two (2) standard deviations (SD) from the target on 1/21/20, 1/22/20, and 1/23/20, 1/24/20, 1/27/20, and twice on 1/28/20 and Lipase tests were performed and reported on patient identified as number 1 on a separate patient identification worksheet on 1/22/20, reported on patient identified as number 2 on a separate patient identification worksheet on 1/23/20, and performed and reported on patients identified as numbers 3,4,5 on 1/27/20. B) In an interview on 9/16/20 at approximately 01:30 PM, the laboratory staff member identified as number four on the CMS 209 form, confirmed that QC performance failed acceptable limits on the days identified above.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Through review of the laboratory's Quality Control Summary Reports for Prothrombin Time assays (PT) and Activated Partial Thrombinplastin Time (APTT) for November 2019 , March 2020, and July 2020, patient result reports and interview it was determined that the laboratory failed to ensure two levels of quality control material are performed every eight hours of patient testing in two of three months reviewed . Findings follow: A) Review of the Quality Control Summary Reports for November 2019 revealed that quality control for PT and APTT assays was performed at 06:15 on 11/6/19 and not attempted again until 05:29 AM on 11/8/19 and QC was performed at 02:15 PM on 11/12/19 and not attempted again until 11/14/19 at 07:54

	AM. B) Review of patient result reports revealed that a PT assay was performed on a patient identified as number 1 on a separate patient identification worksheet at 11:19 PM on 11/6/19, a period of 17 hours since QC was performed, and a PT assay was performed on patient identified as number 2 on a separate patient identification worklist on 11/14/19 at 01:26 AM, a period of over 33 hours since QC was performed. C) Review of the Quality Control Summary Reports for March 2020 revealed that quality control for PT and APTT assays was performed at 06:28 AM on 3 /12/20 and not attempted again until 06:49 AM on 3/16/20. D) Review of patient result reports revealed that a PT assay was performed on a patient identified as number 3 on a separate patient identification worksheet at 09:07 AM on 3/13/20, a period of 27 hours since QC was performed. E) In an interview on 9/16/20 at approximately 10:45 AM, the laboratory staff member identified as number 4 on the CMS 209 form confirmed that the PT assays identified above were performed and reported greater than eight hours since the last succesful performance of quality control.