Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0494205	03/11/2025
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Medical Group	8845 Six Pines Drive, Ste 200, Shenandoah, TX	

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
D0000	An announced survey of the laboratory was conducted on 03/11/2025. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D5300 - 42 C. F.R. 493.1240 Condition: Preanalytic systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) records for the Beckman Coulter DxH 600 hematology analyzer and staff interview, the laboratory failed to ensure preservation of DxH 600 QC records for one of one months requested for review, May 2024. Findings included: 1. Review of laboratory's QC records revealed the laboratory used a DxH 600 Beckman Coulter instrument for hematology testing until August 2024. 2. The laboratory was asked to provide DxH 600 QC records for the month of May 2024 and no such documentation was available for review prior to survey exit. 3. In an interview on 03/11/2025 at 1515 hours in the laboratory, Testing Person number 1 (as indicated on submitted Form CMS 209) stated that the QC records were stored on the instrument (discontinued in August 2024) and thus cannot be retrieved. This confirmed the findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure,

	specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory's submitted test menu, laboratory's policies/procedures, manufacturer's instructions, laboratory's verification studies, patient test statistics and staff interview, the laboratory failed to ensure overall quality of preanalytic systems was maintained for four of four laboratory's testing specialties in 2023 and 2024, hematology, chemistry, diagnostic immunology and urinalysis. Findings included: 1. The laboratory failed to ensure specimen transport temperature was defined and maintained during transport to ensure specimen stability. Refer to D5311. 2. The laboratory failed to ensure instructions to clients defined specimen storage/transport /packaging requirements and/or acceptable transport temperature ranges to maintain specimen integrity. Refer to D5317. 3. The laboratory's quality assurance (QA) failed to identify and correct issues with specimen stability and transport requirements. Refer to D5391.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer instructions, laboratory's specimen stability verification studies, policies/procedures, test records and staff interview, the laboratory failed to ensure specimen transport/storage temperature range was defined and maintained to ensure specimen stability during transport /storage for tests in four of four laboratory's testing specialties in 2023 and 2024, hematology, chemistry, immunology and urinalysis. Findings included: 1. Surveyor observations on 03/11/2025 at 1150 hours in the laboratory revealed the laboratory received samples from outlying facilities in large biohazard bags ("room temperature") and/or insulated cardboard boxes with one medium size icepack. 2. In an interview on 03/11/2025 at 1210 hours in the laboratory, specimen receiving personnel demonstrated a sample that came in the shipment with ice pack, and multiple samples at "room temperature". When asked, she stated that the laboratory does not verify the temperature of the samples upon receipt. She confirmed received samples included test requests for estrogen (estradiol), prostate specific antigen (PSA) and cortisol (chemistry), and samples for hematology, urinalysis and immunologic testing. 3. In an interview on 03/11/2025 at 1215 hours in the hallway, Testing Person number one (as indicated on submitted Form CMS 209) when asked, stated that samples that were not tested immediately were stored in the refrigerator up to seven days. The laboratory did not freeze samples at any time, and never received them frozen. 4. In an interview on 03/11/2025 at 1445 hours in the laboratory the Laboratory Director (as indicated on submitted Form CMS 209) confirmed that

samples for any tests appearing on the laboratory's test menu may be sent for testing to this laboratory from any other sister facility. Samples were transported in coolers or shipped with ice packs, never frozen. 5. Random review of laboratory's test menu revealed the laboratory accepted samples for the following: Estradiol Cortisol Potassium 6. Review of manufacturer instructions for specimen stability for the above tests revealed: a. "Beckman Coulter Access Immunoassay Systems, Access Estradiol Instructions for Use" (document C83775 B, March 2024) stated: "- Store samples tightly stoppered at room temperature (15 to 30C [Degrees Celsius]) for no longer than eight hours. - If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8C. - If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20C or colder." b. "Beckman Coulter Access Immunoassay Systems, Access Cortisol Instructions for Use" (document C58559 D, January 2024) stated: "- Store samples tightly stoppered at room temperature (15 to 30C) for no longer than eight hours. - If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8C. - If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20C or colder." c. "Beckman Coulter Synchron System(s), Potassium K, Chemistry Information Sheet" (document A18509 AT, February 2020) stated: "Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2C to +8C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15C to -20C." 7. Review of laboratory's test verification studies for chemistry immunology, hematology and urinalysis revealed the laboratory did not document verification of specimen stability in transport. 8. Review of laboratory's policy "Specimen Collection, Handling, Transport and Rejection Guidelines" (document GEN-012.02, effective 03/07/2025) revealed: "Each analyte is only stable for a specific length of time period these times vary according to analyte and storage temperature. Please review the stability times listed for each test if specimen stability is in question." And, "Rejection Criteria ... 5. Age of Specimen - Sample stability exceeded, leading to potential degradation. ... 14. Compromised Specimen Integrity - Specimen handling (e.g., not centrifuged, not stored or prepared properly) has affected test validity." And, "REJECTED Specimens Reject the specimens when the content quality or stability has been compromised ..." The stability times listed revealed the policy did not address specific temperature ranges for specimen stability for storage or transport. 9. Review of laboratory's other policies/procedures revealed the laboratory did not define acceptability criteria for samples' storage/transport temperature and/or samples' age at specific temperature ranges, for either of its testing platforms in hematology, chemistry, immunology and urinalysis. There were no written protocols in place for verifying specimen packaging requirements for shipping of samples from other facilities, nor how stability (sample's age versus temperature) was to be verified. 10. Review of random laboratory's test records from November and December 2024 revealed the following samples were tested beyond their stability when stored at refrigerated temperatures: a. Cortisol: Patient: 141892 Sample: 2878 Collected: 10/31 /2024 Tested: 11/04/2024 TAT (turnaround time): 4 days Patient: 289313 Sample: 6813 Collected: 11/07/2024 Tested: 11/11/2024 TAT: 4 days Patient: 333079 Sample: 3034 Collected: 10/28/2024 Tested: 11/01/2024 TAT: 4 days Patient: 357980 Sample: 2752 Collected: 10/31/2024 Tested: 11/06/2024 TAT: 6 days Patient: 358832 Sample: 8497 Collected: 11/13/2024 Tested: 11/19/2024 TAT: 6 days Patient: 73765 Sample: 11996 Collected: 12/06/2024 Tested: 12/10/2024 TAT: 4 days b. Potassium: Patient: 304870 Sample: 3607 Collected: 11/01/2024 Tested: 11/04/2024 TAT: 3 days Patient: 172727 Sample: 3427 Collected: 11/01/20245 Tested: 11/05/2024 TAT: 4 days Patient: 307312 Sample: 3394 Collected: 11/01/2024 Tested: 11/05/2024 TAT: 4 days Patient: 184566 Sample: 3332 Collected: 11/01/2024 Tested: 11/06/2024 TAT: 5 days

	Patient: 226502 Sample: 3598 Collected: 11/01/2024 Tested: 11/07/2024 TAT: 6 days Patient: 246252 Sample: 2109 Collected: 11/01/2024 Tested: 11/08/2024 TAT: 7 days 11. In an interview on 03/11/2025 at 1450 hours in the conference room the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the above findings.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory's test menu, its instructions to client for specimen collection/storage/transport and staff interview, the laboratory failed to ensure its clients had instructions defining specimen handling/storage requirements and specimen packaging instructions to ensure specimen stability was maintained for eight of eight test platforms used by the laboratory in 2023 and 2024 for testing in hematology, chemistry, immunology and urinalysis. Findings included: 1. Review of laboratory's submitted test menu revealed the laboratory performed testing in hematology, chemistry, immunology and urinalysis on the following test platforms: Alere Triage (chemistry) Beckman Coulter DxH 600 and 690T(hematology) Beckman Coulter Access 2 (immunology) Beckman Coulter DxI 9000 (immunology) Beckman Coulter DxC 500 AU (chemistry) iSED Automated ESR (hematology) Arkray AUTION MAX AX-4030 (urinalysis) Beckman Coulter DxU 840m Iris (rinalysis) 2. Review of laboratory's instructions to clients (screen shots of electronic test orders' instructions and a sampling of test labels) revealed the laboratory did not define in its instructions the temperature range requirements for sample's storage (room/ambient or refrigeration), acceptability criteria for specimens' age, nor packaging requirements to maintain the samples' stability (temperature) during transport. 3. In an interview on 03/11/2025 at 1220 hours in the conference room the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory's quality assurance (QA) records, laboratory's policies/procedures and staff interview, the laboratory's QA failed to identify and correct issues with instructions to clients and specimen stability monitoring for eight of eight test platforms used by the laboratory in 2023 and 2024. Refer to D5311 and D5317.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 manufacturer instructions, laboratory's patient test records, test establishment studies and staff interview, the laboratory failed to follow manufacturer instructions for testing prostate specific antigen (PSA) samples from patients 50 years of age or older for 89 of 290 patients tested for PSA in October 2024. Findings included: 1. Review of manufacturer instructions for use "Access Immunoassay Systems, Access Hybriteck PSA" (document D09390 A, September 2024) revealed: "INTENDED USE ... This device is indicated for the measurement of serum PSA in conjunction with digital rectal examination (DRE) as an aid in the detection of prostate cancer in men aged 50 years or older." 2. Review of laboratory's patient PSA test records for October 2024 revealed the following 89 of 290 patients tested for PSA levels in October 2024, did not meet the indicated age criteria for testing: Patient: Date of birth: Age: 178806 06/13/1981 43 232773 12/16/1977 47 335926 08/29/1990 34 200004 10/03/1987 37 318317 08/20/1983 41 322975 10/29/1977 47 178373 04/18 /1977 47 333133 05/02/1990 34 354960 01/02/1979 46 217966 10/10/1982 42 77158 08/09/1979 45 315524 08/02/1975 49 258443 05/15/1990 34 287789 03/27/1979 46 354042 12/29/1978 46 218946 03/05/1981 44 330199 03/20/1980 45 318039 03/24 /1979 46 77796 03/08/1979 46 310869 02/12/1979 46 202685 04/22/1982 42 355039 05/14/1979 45 79880 02/24/1977 48 334790 08/27/1976 48 289176 04/19/1976 49 355377 12/31/1997 27 286935 02/14/1985 40 325085 07/21/1979 45 288598 08/12 /1978 46 45782 07/19/1977 47 355946 02/11/1977 48 354302 08/27/1975 49 297381 04/22/1994 31 245924 12/25/1982 42 175624 12/09/1982 42 349071 12/23/1975 49 356488 09/21/1990 34 327127 02/18/1984 41 296223 10/28/1983 41 339241 04/18 /1983 42 318587 12/27/1982 42 318706 08/21/1979 45 319992 05/22/1979 45 278458 03/09/1977 48 352307 09/25/1976 48 80477 05/04/1976 48 319396 08/10 /1975 49 78797 05/17/1975 49 356583 04/30/1985 39 356668 03/27/1987 42 355577 10/08/1982 42 318435 10/02/1981 43 315707 02/05/1978 47 292622 09/15/1993 31 318404 04/07/1985 40 352968 03/23/1979 46 356157 08/28/1978 46 58120 10/19 /1977 47 316350 11/30/1976 48 76966 10/13/1990 34 356083 05/18/1984 40 238693 11/15/1980 44 288410 11/28/1979 45 321505 12/15/1977 47 314355 04/20/1993 32 356433 11/13/1982 42 352393 03/22/1982 43 75840 08/09/1978 46 275459 02/08 /1978 47 221041 06/25/1977 47 353764 07/29/1988 36 76108 06/03/1983 41 356298 03/20/1983 42 357378 09/08/1980 44 290287 09/01/1977 47 355832 06/28/1977 47 245458 11/04/1975 49 347257 09/06/1975 49 356064 03/15/1984 41 64859 04/19 /1980 45 76892 02/25/1979 46 352666 10/25/1976 48 279130 05/20/1995 29 328160 12/18/1983 41 348718 12/28/1982 42 334919 02/06/1981 44 356154 09/20/1979 45 279034 07/21/1978 46 356732 06/23/1975 49 3. Review of the laboratory's test establishment studies revealed the studies for PSA testing did not address patients age and/or other criteria required for a modified FDA-approved test. 4. In an interview on 03/11/2025 at 12:25 hours in the conference room, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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: Based on review of manufacturer instructions, surveyor's observations and staff interview, the laboratory failed to ensure revised expiration date was documented on two of two Coulter Retic-X controls in use to ensure compliance with manufacturer instructions for stability of the reagents. Findings included: 1. Review of manufacturer's instructions in the Coulter Retic-X package insert (document A63007-AF) revealed: "Assumes that the Instructions for Use section of the package insert is performed a maximum of 18 times within 16 days." 2. Surveyor's observations on 03/11/2025 at 1630 in the laboratory revealed two vials of Coulter Retic-X Cell Control Level 3 (lot: 173224210, expiration date: 2025-04-10) stored in the in-use quality control racks (racks number 00026 and 00056) in the refrigerator. Neither vial was labeled with a revised expiration date or the date of placement into use, therefore it could not be determined how many times the controls were used, or if control's stability was compromised. 3. In an interview on 03/11/2025 at 1635 hours in the conference room, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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: Based on surveyor's observations, review of laboratory's instrument verification studies for the Beckman Coulter DxH 690T hematology analyzer, policies/procedures and staff interview, the laboratory failed to document verification of normal ranges for the laboratory's patient population, one of four verification parameters required for moderate complexity tests. Findings included: 1. Surveyor's observations on 03/11/2025 in the laboratory revealed there were two Beckman Coulter DxH 690T hematology analyzers in use (serial numbers BH18047 and BH23071). 2. Review of laboratory's instrument verification studies for the Beckman Coulter DxH 690T instruments revealed verification studies were completed/approved on 10/28/2024. 3. Further review of the verification studies for the above hematology analyzers revealed neither of the two instruments had documentation of verification of laboratory's reference ranges (normal ranges) for the laboratory's patient population. 4. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place for verification of reference ranges for the laboratory's patient population. 5. In an interview on 03/11/2025 at 1450 hours in the conference room, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency

	specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's hematology analyzer's maintenance records, annual test volumes and staff interview, the laboratory failed to document weekly and monthly maintenance for twenty-three of twenty-three instances maintenance was required in 2023 and 2024. Findings included: 1. Review of manufacturer instructions in the "DxH600 Maintenance Log" (appendix) revealed the following maintenance requirements: "Weekly/As Needed Clean outside of BSV Restart System Manager (computer) Clean the STM (Specimen Transport Module) Clean the AMTC" And, "Monthly Clean PSM fan filter Print and/or Export and delete History Logs Clean the STM Optical Sensors" 2. Review of the "Beckman Coulter UniCel DxH Series Troubleshooting" (document Ver 1.3, November 2016; available online at https://beckmancoultertraining.csod.com/clientimg) revealed: "CBC Parameters ...Out of Range? ... Possible dilution issue? ...Clean Outside of BSV" 3. Review of laboratory's maintenance records for its Beckman Coulter DxH 600 hematology analyzer in use in 2023 and 2024 revealed the following maintenance was not documented: Weekly maintenance not documented for the week of: 06/11/2023 06/18/2023 06/25/2023 07/02/2023 07/09/2023 07/16/2023 07/30/2023 08/06/2023 08/13/2023 08/20/2023 09/03/2023 09/10/2023 09/17/2023 09/24/2023 10/08/2023 10/22/2023 02/04/2024 02/11/2024 02/18/2024 04/14/2024 04/21/2024 08/25/2024 Monthly maintenance not documented: August 2024 4. Review of laboratory's annual test volumes revealed the laboratory performed approximately 218,668 tests annually. 5. In an interview on 03/11/2025 at 1515 hours in the conference room, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory's calibration verification records and staff interview, the laboratory failed to document calibration verification for two of two analyzers for which calibration verification was required in June 2024, the Beckman Coulter AU

	700 and the DxI 800 analyzers. Findings included: 1. Review of laboratory's calibration verification records revealed the laboratory performed calibration verifications every six months for the AU700 (chemistry) and the DxI 800 (immunology) analyzers. 2. Further review of the records revealed calibration verifications for these instruments were documented as follows: AU 700: last calibration verification documented on 12/27/2023 DxI 800: last calibration verification documented on 12/27/2023 Next calibration verifications were due in June 2024, however, there was no documentation of calibration verification in June 2024 for either of the instruments. The instruments were discontinued from use in August 2024. 3. In an interview on 03/11/2025 at 1530 hours in the conference room, the Laboratory Director (as indicated on submitted Form CMS 209) confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of manufacturer instructions, laboratory's records, policies /procedures and staff interview the laboratory's quality assurance (QA) failed to identify and correct issues in analytic systems for five of the eight test platforms utilized by the laboratory in 2023 and 2024. Refer to D5411, D5417, D5421, D5429 and D5439.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's observations, review of manufacturer's instructions, laboratory's records, policies/procedures and staff interview, the Laboratory Director failed to provide overall management of the laboratory for four of four specialties in which the laboratory provided testing services in 2023 and 2024, hematology, chemistry, immunology and urinalysis. Findings included: 1. Laboratory Director failed to ensure laboratory's test systems provided quality results. Refer to D6007. 2. Laboratory Director failed to ensure verification studies were complete. Refer to D6013.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

	This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer's instructions, laboratory's records, policies/procedures and staff interview, the Laboratory Director failed to ensure laboratory's test systems provided quality results for four of four specialties in which the laboratory provided testing services in 2023 and 2024, hematology, chemistry, immunology and urinalysis. Refer to D5300.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of laboratory's records, policies/procedures and staff interview, the Laboratory Director failed to ensure verification studies were complete for one of eight test platforms, the Beckman Coulter DxH 690T hematology analyzer. Refer to D5421.