| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 03D2304817 | 02/17/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Gravitas Surgical Solutions Llc | 2218 N 3rd St, Phoenix, AZ | |

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 |
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| **D0000** | An initial survey was performed on February 17, 2026. The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples D6108 - 42 C.F.R. 493.1409 Condition: Technical Consultant-Moderate Complexity |
| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on lack of Proficiency Testing (PT) records for 2024 and 2025, and the 1st Event of 2026, and an interview with the facility personnel, the laboratory failed to enroll in an HHS approved PT program for regulated testing performed in the specialties of Hematology and Chemistry, which are included in subpart I. Findings include: 1. No documentation was presented for review during the survey conducted on 2/17/26 to indicate the laboratory was enrolled during 2024, 2025, and the 1st Event of 2026 in a CMS-approved PT program for regulated analytes included in subpart I in the specialities of Hematology and Chemistry. 2. The laboratory performs testing for the following regulated analytes: Hemoglobin, Hematocrit, Chloride, Glucose, Potassium, Sodium, PCO2 blood gas, pH blood gas, PO2 blood gas, blood urea nitrogen (BUN), and Creatinine. 3. The facility personnel interviewed on 2/17/26 at 8:45 AM confirmed the laboratory was not enrolled in a CMS-approved PT |

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| | program in 2024, 2025, and the 1st Event of 2026 in the specialities of Hematology and Chemistry. 4. This laboratory began patient testing utilizing the I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of accuracy verification documentation for review and interview with the facility personnel, the laboratory failed to verify the accuracy of analytes not included in subpart I at least twice annually during 2024 and 2025. Findings include: 1. No documentation was presented for review during the survey conducted on 2/17 /26 to indicate the laboratory verified the accuracy of Lactate, Activated Clotting Time (ACT), TCO2, HCO3, BE, SO2, Anion Gap, and Ionized Calcium testing at least twice annually during 2024 and 2025. 2. The facility personnel interviewed on 2 /17/26 at 8:45 AM confirmed the laboratory failed to verify the accuracy of the analytes indicated above at least twice annually during 2024 and 2025. 3. This laboratory began patient testing utilizing the I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on a lack of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. This laboratory began patient testing in June 2024 utilizing the I-Stat analyzer under the specialties of Chemistry and Hematology with a reported annual test volume of 14,400. 2. No QA documentation was provided for review during the survey conducted on 02/17/2026 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the general laboratory system requirements specified at 493.1231 through 493.1236, including but not limited to, Proficiency Testing policies and procedures. 3. The facility personnel interviewed on 2/17/26 at 9:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the general laboratory systems requirements. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b) |

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| | (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of a procedure manual and interview with the facility personnel, the laboratory failed to have a procedure manual in place that includes the information required under 493.1251. Findings include: 1. The laboratory began patient testing in June 2024 utilizing the I-Stat analyzer to perform patient testing under the specialities of Chemistry and Hematology with an annual test volume of 14,400. 2. The laboratory failed to provide a procedure manual that included the following procedures on the survey date of 2/17/26: - 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. -Step-by-step performance of the procedure, including test calculations and interpretation of results. -Preparation of solutions, calibrators, controls, reagents, and other materials used in testing. -Calibration and calibration verification procedures. -The reportable range for test results for the test system as established or verified in 493.1253. See D5421 for specific findings. -Control procedures. -Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. -Limitations in the test methodology, including interfering substances. -Reference intervals (normal values). -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. -Description of the course of action to take if a test system becomes inoperable. 3. The facility personnel interviewed on 2/17/26 at 8:30 AM confirmed the laboratory failed to provide a procedure manual with the required elements listed above. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>(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 |

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| | the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of performance specification documentation for Arterial Blood Gas (ABG), Chem8+ panel, and Activated Clotting time (ACT) testing performed on the I-Stat analyzers and interview with the facility personnel, the laboratory failed to verify the performance specifications for the I-Stat analyzers, including accuracy, precision, reportable range and reference range, prior to reporting patient test results. Findings include: 1. The laboratory utilizes three test cartridges on eight I-Stat analyzers for patient testing. These include: CG4+ (for ABG testing), Chem8+ and ACT cartridges: - The CG4+ cartridge includes the following analytes: Lactate, pH, pCO2, pO2, TCO2, HCO3, Base Excess (BE) and SO2. - The Chem8+ cartridge includes the following analytes: Sodium, Potassium, Chloride, Glucose, Ionized Calcium, Urea Nitrogen (BUN), Creatinine, Anion Gap, Hematocrit (HCT) and Hemoglobin (HGB). - The ACT cartridge includes the test: Activated Clotting time (ACT). 2. No documentation was presented for review for each I-Stat analyzer to indicate the laboratory obtained performance specifications comparable to those established by the manufacturer prior to reporting patient test results, including accuracy, precision, reportable range and reference range. 3. The testing personnel interviewed on 2/17/26 at 9:30 AM confirmed the laboratory failed to provide evidence of the verification of performance specifiications for each of the I-Stat analyzers. 4. The laboratory began patient testing in June 2024 utilizing the I-Stat analyzers under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) 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 do the following:<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of I-Stat test records and interview with the facility personnel, the laboratory failed to perform and document the electronic simulator check on each day of patient testing. Findings include: 1. This laboratory began patient testing utilizing 8 I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. 2. The laboratory failed to provide documentation to indicate the electronic simulator check was performed prior to patient testing on each day of patient testing from June 2024 through the survey date of 2/17/26. 3. The facility personnel interviewed on 2/17/26 at 8:30 AM confirmed the laboratory failed to perform the electronic simulator check on the I-Stat analyzer on each day of patient testing from June 2024 through the survey date of 2/17/26. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>(d) Unless CMS Approves a procedure, specified in Appendix C of the State |

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| | 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required for testing performed under the specialties of Chemistry and Hematology. Findings include: 1. The laboratory utilizes three test cartridges on eight I-Stat analyzers for patient testing. These include: CG4+ (for ABG testing), Chem8+ and ACT cartridges: - The CG4+ cartridge includes the following analytes: Lactate, pH, pCO2, pO2, TCO2, HCO3, Base Excess (BE) and SO2. - The Chem8+ cartridge includes the following analytes: Sodium, Potassium, Chloride, Glucose, Ionized Calcium, Urea Nitrogen (BUN), Creatinine, Anion Gap, Hematocrit (HCT) and Hemoglobin (HGB). -The ACT cartridge includes the test: Activated Clotting time (ACT). 2. The laboratory failed to perform two levels of external quality control each day of patient testing for testing performed on the I-Stat analyzer from June 2024 through the survey date of 2/17/26. 3. On the date of the survey, the laboratory had not established Individualized Quality Control Plans (IQCP) for testing utilizing the CG4+, Chem8+, and ACT cartridges. 4. The facility personnel interviewed on 2/17/26 at 9:15 AM confirmed the laboratory failed to perform and document two levels of external control material each day of patient testing and had not created IQCPs for the test cartridges listed above. 5. This laboratory began patient testing utilizing the I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to establish QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. No QA documentation was provided for review during the survey conducted on 2/17/26 to indicate the laboratory established policies and procedures to monitor, assess and, when indicated, correct problems identified in the analytic systems specified at 493. 1231 through 493.1236. 2. The facility personnel interviewed on 2/17/26 at 10:00 AM confirmed the laboratory failed to provide documentation of an established QA policy and procedure to monitor, assess and correct problems identified in the analytic |

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| | systems. 3. This laboratory began patient testing utilizing the I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(ii)<br><br>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of performace documenation data presented for review, the director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. See D5421 for findings. |
| **D6015** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)<br><br>(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--<br><br>This STANDARD is not met as evidenced by:<br>The laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program from June 2024 through the survey date of 2/17 /26 for testing of the regulated analytes, Hemoglobin, Hematocrit, Chloride, Glucose, Potassium, Sodium, PCO2 blood gas, pH blood gas, PO2 blood gas, blood urea nitrogen (BUN), and Creatinine, under the specialties of Hematology and Chemistry. See D2000 for findings. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Quality Control documentation and review of the Quality Control Plan (QCP) for the CG4+, Chem8+, and ACT test cartridges, the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. See D5445 for findings. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test |

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| | performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of written documentation for review and interview with the facility personnel, the laboratory director failed to specify, in writing, the responsibilities and duties of all laboratory personnel engaged in the performance of the preanalytic, analytic and postanalytic phases of testing. Findings include: 1. No written documentation was presented for review to indicate the laboratory director specified, in writing, the responsibilities and duties of all laboratory personnel engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results 2. The facility personnel interviewed on 2/17/26 at 9:15 AM confirmed that the laboratory failed to provide evidence of written documentation specifying the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing as indicated above. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPLEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>The Condition of Technical Consultant was found to be not met based on the failure of the laboratory to have a Technical Consultant who provides technical oversight as evidenced by: D6035- failure to have a Technical Consultant who meets the qualification requirements of 493.1411; D6053- failure to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens; and D6054- failure to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually. |
| **D6035** | TECHNICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1411<br><br>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical |

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| | oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of a qualified technical consultant (TC) at the time of the survey conducted on 2/17/26 and interview with the facility personnel, the laboratory failed to have a qualified TC who meets the qualification requirements for a moderate complexity laboratory performing patient testing from June 2024 through the date of survey. Findings include: 1. During the survey conducted on 2/17/26, the laboratory presented the CMS 209 Laboratory Personnel Form listing one individual as the TC. The individual listed did not have the education and experience required under 493.1411 to qualify as the TC. 2. The facility personnel interviewed on 2/17/26 at 8:15 AM confirmed that the laboratory did not have a qualified TC at the time of the survey. 3. This laboratory began patient testing utilizing the I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of performance evaluation documentation, lack of a qualified technical consultant and interview with the facility personnel, the laboratory failed to evaluate |

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| | and document the performance of one out of one testing personnel at least semiannually during the first year the individuals tested patient specimens utilizing the I-Stat analyzer. Findings include: 1. No semiannual competency evaluation documentation was presented for review for five of five testing personnel. 2. The facility personnel interviewed on 2/17/26 at 8:15 AM confirmed the laboratory failed to perform and document a semiannual competency evaluation for the testing personnel indicated above. 3. This laboratory began patient testing utilizing the I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Thereafter, evaluations must be performed at least annually<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of performance evaluation documentation, lack of a qualified technical consultant and interview with the facility personnel, the laboratory failed to evaluate and document the performance of one out of one testing personnel at least annually during the first year the individuals tested patient specimens utilizing the I-Stat analyzer. Findings include: 1. No annual competency evaluation documentation was presented for review for five of five testing personnel. 2. The facility personnel interviewed on 2/17/26 at 8:15 AM confirmed the laboratory failed to perform and document an annual competency evaluation for the testing personnel indicated above. 3. This laboratory began patient testing utilizing the I-Stat analyzers in June 2024 under the specialities of Chemistry and Hematology with a reported annual test volume of 14,400. |