Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2051920	11/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Westside Surgical Hospital, Llc	4200 Twelve Oaks Place, Houston, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6056 - 42 C.F.R. 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: A. Based on review of manufacturer's instructions for the Eurotrol Glucotrol-AQ quality control material, surveyor observation of control material currently in use, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory performed quality control testing utilizing expired quality control material. The findings were: 1. A review of the manufacturer's instructions for the Eurotrol Glucotrol-AQ quality control material (AN01326) under the section titled "Storage and stability" revealed: "After opening the vial, Glucotrol-AQ is stable for 1 month when properly closed and stored at 2 - 30C." 2. Surveyor observation of control material currently in use in the laboratory on 11/27/2018 at 1130 hours revealed the following: a) Glucotrol-AQ Low control lot: 74737 opened: 09/12/18 b) Glucotrol-AQ High control lot: 74739 opened: 09/12/18 Thus the control material had

	been expired since 10/12/2018 3. A review of the laboratory quality control records from November 2018 revealed the expired control material was used on the following 21 days: 11/1 11/2 11/5 11/8 11/9 11/10 11/11 11/12 11/13 11/14 11/15 11/16 11/17 11/18 11/19 11/20 11/21 11/22 11/23 11/24 11/25 11/26 11/27 - 1st run 11/27 - 2nd run 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/27/2018 at 1130 hours in the laboratory - after her review of the records - confirmed the findings. 25846 B. Based on review of the manufacturer's instructions for the Consult hCG Combo Cassette Test; BD Vacutainer tubes, surveyor observation of stored test kits and supplies, and staff interview, it was revealed the hospital failed to follow the manufacturer's instructions for ensuring the proper storage temperature of test kits and supplies tn the emergency room area. The findings were: 1. A review of the manufacturer's instructions for the Consult hCG Combo Cassette Test revealed the manufacturer required the test kits to be stored in an environment where the temperature was 2 - 30C. 2. A review of the manufacturer's instructions for the BD Vacutainer tubes revealed the manufacturer required the test kits to be stored in an environment where the temperature was 4 - 25C. 2. Surveyor observation of test kits and supplies stored in the Emergency Room area on 11/27 /2018 at 0935 hours revealed the following kits and supplies were stored: 1 box Consult hCG Combo Cassette Test BD Vacutainer SST (ref 367988) BD Vacutainer K2EDTA Tubes (ref 367856) There was not documentation of the temperature of the room being monitored to ensure the temperature stayed within the manufacturer's requirements. 3. In an interview of the Administrator/CNO on 11/27/2018 at 0937 hours, she stated that the room was electronically monitored. The Administrator/CNO was asked to provide documentation of monitoring the temperature where the products were stored. 4. An interview with the Administrator/CNO on 11/27/2018 at 1009 hours revealed the hospital did not electronically monitor the temperature of the emergency room. This confirmed the findings. C. Based on observation of laboratory supplies available for use at the facility at the time of the survey and interview of facility personnel it was revealed that the hospital failed to ensure that expired supplies were not available for use in the emergency room area. Findings were: 1. Observation of the laboratory supplies available for use at the time of the survey on 09 /06/2013 revealed the following supplies were expired: 20 tubes BD Vacutainer K2EDTA Tubes (ref 367856) expired 2018-10-31 3 swabs Coplan Transystem (lot 1080c) expired 2018/10 2. An interview of the Administrator/CNO on 11/27/2018 at 0935 hours in the emergency room and after the facility representative's own observation of the supplies the above findings were confirmed. Key hCG - human chorionic gonadotropin BD- Becton, Dickinson and Company
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 and 2018, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 3 of 11 attestation statements and testing personnel signing 3 of 10 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2017 (hematology events 1, 2, and 3, and chemistry events 1, 2,

	and 3) and 2018 (hematology events 1 and 2, and chemistry events 1, 2 and 3) revealed the following missing signatures: a) Laboratory director 2018 Chemistry event 2 2018 Chemistry event 3 2018 Hematology event 2 b) Testing personnel 2018 Chemistry event 3 2018 Hematology event 1 2018 Hematology event 2 2. The laboratory was asked to provide documentation of the missing signatures on attestation statements. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/27/2018 at 1135 hours in the laboratory - after her review of the records - confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/12/2017
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2017 and 2018, and staff interview, it was revealed the laboratory failed to have documentation of the review of results for 3 of 11 events. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing results from 2017 (hematology events 1, 2, and 3, and chemistry events 1, 2, and 3) and 2018 (hematology events 1 and 2, and chemistry events 1, 2 and 3) revealed the following were missing documentation of review: 2018 Chemistry Event 2 2018 Chemistry Event 3 2018 Hematology Event 2 2. The laboratory was asked to provide documentation of the review of the identified results. No documentation was provided. 3. An interview with testing personnel number 4 (as listed on Form CMS 209) on 11/27/2018 at 1135 hours - after her review of the records- confirmed the findings.
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 a review of the laboratory's procedure manuals and staff interview, it was revealed that the Quality Monitoring Plan (PI. 005) and Quality Assurance Indicators (PI.006) procedures were not approved, signed and dated by the new laboratory director. The findings were: 1 A review of the laboratory procedure manuals revealed they were not approved, signed and dated by the current laboratory director. The procedures without documentation of laboratory director review and approval were: a) Quality Monitoring Plan (PI. 005) (signed by previous laboratory director on 1-04-17) b) Quality Assurance Indicators (PI.006) (signed by previous laboratory director on 1-04-17) 2. An interview with the primary testing person on 11/27/218 at 1335 hours in the laboratory she revealed the new laboratory director started on 10/05/218 but did not sign the quality assurance procedures.
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 a review of the CMS-209 Laboratory Personnel Report, CMS-116, laboratory records and confirmed in interview the laboratory failed to employ personnel to provide overall management and direction of the laboratory that met the qualifications of laboratory director for the moderate complexity tests performed from 09/05/2018 to the date of the survey 11/27/2018. (refer to D6003) This is a repeat deficiency from the survey conducted on 04/12/2017. Key: CMS- Centers for Medicare & Medicaid Services
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 possess qualifications that are equivalent to those required for such certification; 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have

qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:
Based on a review of the CMS-209 Laboratory Personnel Report, laboratory records

	and confirmed in interview the laboratory failed to employ personnel to provide overall management and direction of the laboratory that met the qualifications of laboratory director for the moderate complexity tests performed from 09/05/2018 to the date of the survey 11/27/2018. Findings were: 1. A review of the CMS-209 Laboratory Personnel Report dated 11/27/2018 and signed by the current laboratory director on 11/28/2018 revealed the laboratory director held the position effective 10 /05/2018. The former laboratory director end date was 9/04/2018. There was no documentation of a laboratory director for the time period of 9/05/2018 to 10/04/2018. 2. In an interview of the Administrator/CNO on 11/27/2018 at 1300 hours in the laboratory she confirmed the above findings. She stated there were financial issues. 3. A review of the records submitted for laboratory director (effective 10/05/2018) revealed no documentation he met the education requirements for moderate complexity testing. The only documentation submitted was a contract and Curriculum Vitae. No supporting documentation was available for review. 4. In an email sent by the state agency on 10/24/2018 at 1529 hours to the Administrator/CNO "Please send your LD board certification documents and fill out the attached form [Qualification Appraisal form] (include credentials) for your histology technical supervisor." 5. In an email sent by the Administrator/CNO on 11/20/2018 at 0936 am she stated that he was a "certified CAP lab director. I am awaiting his a copy of his certificate, then will forward to you." 6. In an interview of the Administrator/CNO on 11/27/2018 at 1300 hours in the laboratory she confirmed that the only credentials submitted were a Curriculum Vitae. She stated she had asked for documentation of education, but had not received anything. 7. A review of patient logs from 09/05/2018 to 11/27/2018 revealed the facility had performed 112 moderate complexity chemistry and hematology tests during the time period they had no technical consultant. Please refer to patient alias list. This is a repeat deficiency from the survey conducted on 04/12 /2017. Key: CMS- Centers for Medicare & Medicaid Services
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing results from 2017 and 2018, and staff interview, it was revealed the laboratory director failed to ensure the review of results for 3 of 11 events (refer to D5211).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of laboratory quality assessment (QA) records and interview of facility personnel it was revealed that the laboratory director failed to assure that quality assessment programs were maintained. Findings were: 1. A review of QA records available for review at the time of the survey on 11/27/2018 revealed that the facility had a documented QA policy requiring monthly records but no documented QA maintenance records for 6 of 10 months in 2018 (May through October 2018). 2. An interview of the primary testing person on 11/27/2018 at 1333 hours in the laboratory office confirmed the above findings
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on a review of the Directed Plan of Correction from the 04/12/2017 survey, CMS-209 Laboratory Personnel Report, laboratory records, and confirmed in interview the facility failed to adhere to the Directed Plan of Correction and employ personnel to provide Technical supervision that met the qualifications of technical consultant for the moderate complexity tests performed from 09/05/2018 to the date of the survey 11/27/2018. (refer to D6035) This is a repeat deficiency from the survey conducted on 04/12/2017. Key: CMS- Centers for Medicare & Medicaid Services
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (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 possess qualifications that are equivalent to those required for such certification; 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 one year of laboratory training or experience, or both in non-waived 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 oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or

biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on a review of the Directed Plan of Correction from the 04/12/2017 survey, CMS-209 Laboratory Personnel Report, laboratory records, and confirmed in interview the facility failed to adhere to the Directed Plan of Correction and employ personnel to provide Technical supervision that met the qualifications of technical consultant for the moderate complexity tests performed from 09/05/2018 to the date of the survey 11/27/2018. Findings were: A. Failed to adhere to the Directed Plan of Correction from the 04/12/2017 survey. 1. A review of the Directed Plan of Correction from the 04/12/2017 survey revealed the hospital was directed to: "Obtain the services of a qualified Technical Consultant (from outside of the facility) to assist and review the laboratory's performance. Any prospective candidate must hold a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and possess at least four (4) years of laboratory experience in the specialty(s) of Bacteriology, Mycology, Parasitology, General Immunology, Routine Chemistry, Endocrinology, and Hematology." "If there is a change in the technical consultant(s), the laboratory must inform the State Agency and CMS of the change in personnel, the effective date, the duration of the new contract, and provide documentation of credentials. There must be State approval of this change prior to the official change in technical consultant(s)." "Once compliance has been achieved, the technical consultant must be on premises monthly." "The duties of the Technical Consultant include:" "e) Implement procedures for the review of proficiency testing to include documentation of remedial actions for any unacceptable analyte and test event scores;" "j) Evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation." 2. A review of the CMS-209 Laboratory Personnel Report dated 11/27/2018 and signed by the current laboratory director on 11/28/2018 revealed the laboratory director held the position of technical consultant for Hematology and Chemistry effective 10/05/2018. The former technical consultant end date was 9/04/2018. There was no documentation of a technical consultant for the time period of 9/05/2018 to 10/04/2018. 3. A review of the credentials submitted for the current technical consultant (effective 10/05/2018) revealed a Curriculum Vitae with no supporting educational documents. There was no documentation for review to ensure he met the educational requirements or experience requirements of at least four (4) years of laboratory experience in the specialty(s) of Bacteriology, Mycology, Parasitology, General Immunology, Endocrinology, and Hematology. 4. A review of the consultant termination letter effective 09/04/2018, the Laboratory Professional Agreement effective October 5th, 2018 for the new technical

	consultant and laboratory records revealed no documentation that the hospital had notified the State Agency and CMS of the change in personnel, the effective date, the duration of the new contract, and provide documentation of credentials prior to the change in technical consultant. In addition, there was no documentation of State approval of the new technical consultant prior to the change. 5. A review of monthly documented visits of the technical consultant revealed no documentation of monthly visits for 3 of 11 months in 2018. (July, August and September 2018). In addition, a review of the current technical consultant Laboratory Professional Agreement revealed the terms of the contract did not specify technical consultant monthly visits. The agreement stated "Laboratory director will visit the facility a minimum of once every 3 months for a maximum of 6 hours." 6. The hospital failed to follow the directed plan of correction for technical consultant review of proficiency testing. (refer to D5211). 7. The hospital failed to follow the directed plan of correction for technical consultant evaluating the competency of testing persons. (refer to D6046) B. Failed to employ personnel to provide Technical supervision that met the qualifications of technical consultant for the moderate complexity tests performed from 09/05/2018 to the date of the survey 11/27/2018. 1. A review of the CMS-209 Laboratory Personnel Report dated 11/27/2018 and signed by the current laboratory director on 11/28/2018 revealed the laboratory director held the position of technical consultant for Hematology and Chemistry effective 10/05/2018. The former technical consultant (who was also the laboratory director) end date was 9/04/2018. There was no documentation of a technical consultant for the time period of 9/05/2018 to 10/04 /2018. 2. In an interview of the Administrator/CNO on 11/27/2018 at 1300 hours in the laboratory she confirmed the above findings. She stated there were financial issues. 3. A review of the credentials submitted for current technical consultant (effective 10/05/2018) revealed no documentation he met the requirements of education and laboratory experience in the specialty of Hematology or Chemistry. 4. In an interview of the Administrator/CNO on 11/27/2018 at 1300 hours in the laboratory she confirmed that the only credentials submitted were a Curriculum Vitae. She stated she had asked for documentation of education, but had not received anything. 5. A review of patient logs from 09/05/2018 to 11/27/2018 revealed the facility had performed 112 moderate complexity chemistry and hematology tests during the time period they had no technical consultant. Please refer to patient alias list. This is a repeat deficiency from the survey conducted on 04/12/2017. Key: CMS-Centers for Medicare & Medicaid Services
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on 4 of 5 testing personnel in 2018. 1. A review of the laboratory's personnel records revealed competency assessments performed in 2018 on 4 of 5 testing personnel were performed by someone other than the technical consultant, and this person did not meet the qualifications of a technical consultant. They were (as listed on Form CMS 209): a) Testing personnel 2 performed: 02/03/18 by: testing personnel 1 b) Testing personnel 3 performed: 01/08/18 by: testing

	personnel 1 c) Testing personnel 4 performed: 02/23/18 by: testing personnel 1 d) Testing personnel 5 performed: 08/26/18 by: testing personnel 1 2. The laboratory was asked to provide documentation of the technical consultant assessing the competencies of testing personnel for 2018. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/27 /2018 at 1410 hours in the laboratory revealed she performed the competency assessments. This confirmed the findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/12/2017
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: Based on a review of the CMS-209 Laboratory Personnel Report, laboratory records and confirmed in interview the laboratory failed to employ personnel to provide clinical consultation services that met the qualifications of laboratory clinical consultant for the moderate complexity tests performed from 09/05/2018 to the date of the survey 11/27/2018. (refer to D6057) This is a repeat deficiency from the survey conducted on 04/12/2017. Key: CMS- Centers for Medicare & Medicaid Services
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on a review of the CMS-209 Laboratory Personnel Report, Laboratory Professional Services Agreement, laboratory records and confirmed in interview the laboratory failed to employ personnel to provide clinical consultation services management for the laboratory that met the qualifications of laboratory clinical consultant for the moderate complexity tests performed from 09/05/2018 to the date of the survey 11/27/2018. Findings were: 1. A review of the CMS-209 Laboratory Personnel Report dated 11/27/2018 and signed by the current laboratory director on 11 /28/2018 revealed the position of clinical consultant was not filled. The former clinical consultant (who was also the laboratory director) end date was 9/04/2018. 2. A review of the Cancellation of Laboratory Director Position dated 09/07/2018 stated: "This letter is to inform you that I have canceled the laboratory directorship service to Westside Surgical Hospital as up to September 4, 2018." 3. A review of the Laboratory Professional Agreement effective October 5th, 2018 revealed the new laboratory director was not contracted for the position of clinical consultant: "Scope of Services" "e) Pathologist shall be available and responsible for clinical consultant duties in the lab as may from time to time be reasonably required to provide proper

	clinical consultation. In the event Pathologist is unavailable too provide such services, [consulting service] will assign a substitute consultant to provide coverage to the laboratory." and "Pathologist Assigned: To be determined." "Clinical Consultant duties performed by the pathologist:" 3. A review of patient logs from 09/05/2018 to 11/27/2018 revealed the facility had performed 112 moderate complexity chemistry and hematology tests during the time period they had no clinical consultant. Please refer to patient alias list. 4. In an interview of the Administrator/CNO on 11/27/2018 at 1300 hours in the laboratory she confirmed the above findings. She stated that "they were looking for one". This is a repeat deficiency from the survey conducted on 04/12 /2017. Key: CMS- Centers for Medicare & Medicaid Services CBC- Complete Blood Count BMP+- Piccolo Basic Metabolic Panel Plus Piccolo Basic Metabolic Panel Plus- calcium, chloride, creatinine, glucose, lactate dehydrogenase, magnesium, potassium, sodium, total carbon dioxide, and blood urea nitrogen