Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2044825	02/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Healthbanks Biotech Usa, Inc	185 Technology Dr Ste 150, Irvine, CA	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's personnel competency evaluation documents, and interview with the laboratory manager on February 9, 2024, at 1:30 pm, the laboratory failed to establish and follow written policies and procedures to assess employees. The findings include: 1. The laboratory did not have any competency records for the testing person #1 for the years 2022 and 2023. The testing person #2 had competency evaluation, however it was incomplete and did not cover all the 6 items listed in the subpart M. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2. The laboratory manager on February 9, 2024, at 1:30 pm, affirmed that the laboratory did not evaluate testing person #1 competency in 2022 and 2023. 3. The laboratory's testing declaration form stated that the laboratory performed approximately 648 tests, annually.
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 Surveyor review of laboratory's proficiency testing records, and interview

	with the laboratory manager on February 9, 2024, at 1:10 pm, the laboratory failed to review and evaluate the proficiency testing results. The findings include: 1. The laboratory participated in the CAP proficiency testing program in 2022 and 2023. The laboratory's % CD34+ result for the sample FL4-03 was unacceptable. The laboratory did not review the unacceptable result and did not take any action. Furthermore, some results from 2022 was reviewed on August 30, 2023, by an unauthorized individual but no action taken when the bacterial culture test result for the sample CBT-02 lacked the consensus for the evaluation. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2. The laboratory manager on February 9, 2024, at 1:10 pm, affirmed that the laboratory did not review and evaluate the 2022 and 2023 proficiency testing results by the appropriate staff. 3. The laboratory's testing declaration form stated that the laboratory performed approximately 648 tests, annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, personnel competency evaluation documents, proficiency testing records, and interview with the laboratory manager on February 9, 2024, at 1:30 pm, the laboratory failed to establish the quality assessment for the general laboratory system. The findings include: The laboratory did not have a system in place to assess the quality of its work. Quality assessment is an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions at all location/sites where testing is performed. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. QA of the Analytic System includes assessing: Test procedures; Accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; Specimen and reagent storage condition; Equipment/instrument/test/system maintenance and function checks; Establishment and verification of method performance specifications; Calibration and calibration verification; Control procedures; Comparison of test results; Corrective actions; and Test records. Therefore, the accuracy of the patients' test results cannot be assured and have potential to harm patients.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and

	493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, personnel competency evaluation documents, proficiency testing records, and interview with the laboratory manager on February 9, 2024, at 1:30 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D5209, D5211, D5291 and D6170.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 Surveyor review of laboratory's proficiency testing records, and interview with the laboratory manager on February 9, 2024, at 1:10 pm, the laboratory director failed to review and evaluate the proficiency testing results. The findings include: See D5211.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's testing process and interview with the laboratory manager on February 9, 2024, at 1:23 pm, the laboratory director failed to ensure that all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered. The findings include: See D6170.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

	This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, personnel competency evaluation documents, and interview with the laboratory manager on February 9, 2024, at 1:30 pm, the laboratory director failed to ensure that the laboratory established policies and procedures for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. The findings include: See D5209.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, proficiency testing records, personnel competency evaluation documents, job descriptions, and interview with the laboratory manager on February 9, 2024, at 1:30 pm, the laboratory director failed to specify, in writing, the responsibilities and duties of each individual involved in the laboratory operation including consultants and supervisors. The findings include: The laboratory had 1 State licensed and 1 unlicensed testing personnel, 1 unlicensed consultant and 1 unlicensed CEO. None of them had approved duties and responsibilities in writing from the laboratory director. The laboratory's proficiency testing records showed that the CEO reviewed and signed the documents. Therefore, the accuracy of the laboratory's test results produced by the unauthorized personnel cannot be assured and might have had harmed patients.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's testing process and interview with the laboratory manager on February 9, 2024, at 1:23 pm, the laboratory failed to use the California State licensed testing personnel who performed high complexity testing. The findings include: 1. The laboratory performed high complexity testing such as, blood culture, blood cell separation, flow cytometry and cell counts. The laboratory had 2 testing personnel. The testing person #1 had the State license but the testing person #2 did not have the State license. The testing person #2 who also served as the laboratory manager claimed to assist the testing person #1, however it was determined

	from the documentation and interview that the testing person #2 was performing various high complexity tests. Therefore, the accuracy of the laboratory test results cannot be assured and may have potential to harm patients. 2. The laboratory manager on February 9, 2024, at 1:23 pm, affirmed that the testing person #2 did not have the State license. 3. The laboratory's testing declaration form stated that the laboratory performed approximately 648 tests, annually.