DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	7/28/2026-7/29/2026
	FEI NUMBER 1938095

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Thomas F. Buck, President

FIRM NAME	STREET ADDRESS
Sure-Tech Diagnostic Associates, Inc	12115 Tesson Ferry Professional Ctr
CITY, STATE, ZIP CODE, COUNTRY Saint Louis, MO 63128-1250	TYPE ESTABLISHMENT INSPECTED Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The quality management system documentation does not include required procedures and records.

Specifically,

A. During the inspection, no documented risk management process was identified as required by ISO 13485:2016 § 7.1.

B. A Medical Device File has not been established for Fetal Hemoglobin Controls, a medical device developed and commercially released in 2024. Required documentation — including design inputs, design outputs, risk management records, and verification/validation records — was not available during inspection.

C. Your firm has not established documented procedures for the evaluation and selection of suppliers, as required by ISO 13485:2016 § 7.4.1. No written supplier qualification procedure was identified during inspection.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Edward E Lockwood, Investigator

X Edward E Lockwood
Investigator
Signed By: EDWARD E. LOCKWOOD -S
Date Signed: 07-29-2026 10:29:42

DATE ISSUED
7/29/2026

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edward E Lockwood, Investigator	X Edward E Lockwood Investigator Signed By: EDWARD E. LOCKWOOD -S Date Signed: 07-29-2026 10:29:42	7/29/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."