DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	2/4/2026-2/9/2026* FEI NUMBER 3002619777

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
John A. Romans, CEO	
FIRM NAME Collaborative Care Diagnostics, LLC.	STREET ADDRESS 860 Blue Gentian Rd. Ste 195
CITY, STATE, ZIP CODE, COUNTRY Eagan, MN 55121-1655	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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

One or more processes for risk management in product realization have not been adequately documented.

Specifically,

DP-04-007, FMEA Analysis, Rev. C (effective 02/05/2026) and DP04-004, HAZARD Analysis, Rev. F (effective 09/05/2017)—your firm's processes established and implemented to control risk during the product realization process—do not ensure that all reasonably foreseeable hazards and harms are identified and addressed in a consistent manner.

- FMEA documents relating to the design of your PADnet 4.0 and PADnet Xpress products do not identify any risks associated with the software included with, and necessary for, correct intended operation of the products.
- DP04-007 Appendix B specifies criteria for instituting risk control measures; however, these are inconsistent with criteria specified in TR-284, PADnet Xpress Risk Management Plan, Rev. A (effective 12/06/2019) for the PADnet Xpress or TR-225, PADnet 4.0 Risk Management Plan, Rev. A (effective 06/05/2017)

OBSERVATION 2

Review of design and development changes did not include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tyler R Courtney, Investigator	X Tyler R Courtney Investigator Signed By: Tyler R. Courtney -S Date Signed: 02-09-2026 17:52:26	2/9/2026

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Specifically,

SP04, Design Control, Rev. Q (effective 02/03/2026) and SP29, Software Development, Rev. D (effective 02/05/2026)—your established processes for controlling design and development changes have not been implemented to ensure that all changes are evaluated for potential impact to product in the field and to any applicable regulatory submissions.

- For example, no formal change significance evaluations have been performed for changes made to software versions relating to the PADnet 4.0 and PADnet Xpress products.

Additionally, a change was made to update your current label for the PADnet Xpress from Rev. F to Rev. G to include the product identifier portion of the unique device identifier in both human readable and AIDC formats, however, this change did not include a formal impact assessment.

OBSERVATION 3

The medical device(s) label did not have a unique device identifier (UDI) present in easily readable plain-text and automatic identification and data capture (AIDC) technology.

Specifically,

No variable production identifier portion of the unique device identification was present in either a human readable or AIDC format for your firm's PADnet Xpress product for any revision of the label since commercialization on 07/09/2021 to include Rev. E and Rev. F.

OBSERVATION 4

The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided.

Specifically,

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John A. Romans, CEO

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No data relating to the PADnet Xpress was uploaded into the Global Unique Device Identification Database including device identification or production identification information obtained by your issuing agency.

***DATES OF INSPECTION**

2/04/2026(Wed), 2/05/2026(Thu), 2/06/2026(Fri), 2/09/2026(Mon)

AMENDMENT 1

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Reported corrected, not verified

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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."