



BIO-RAD LABORATORIES
 Clinical Systems Division
 4000 Alfred Nobel Drive
 Hercules, California 94547

CERTIFICATE OF ANALYSIS

PRODUCT:	D-10™ HbA1c Reorder Pack
CATALOG NUMBER:	12000949

CONTROL NUMBER:	64541130
EXPIRATION DATE:	2024-08-06
DATE OF MANUFACTURE:	2023-04-17

CALIBRATOR INFORMATION

Component	Material #	Control Number	Expiration Date
Calibrator/Diluent Set	12005706	S30111	2024-11-30

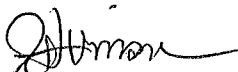
Analyte	QSD Control Lot	Level	Specification Range (%)	Control Result (%)
HbA1c	89231	1	4.3 – 5.8	5.2
	89232	2	7.6 – 9.9	8.8

Component	Material #	Control Number	Expiration Date
Buffer 1	220-0110	AA30092	2025-03-12
Buffer 2	220-0111	AA30093	2025-03-09
Wash/Diluent Reagent	220-0112	AA30078	2025-02-28
Analytical Cartridge	12005707	R00345AJ	2024-08-06
Whole Blood Primer	220-0148	64530228	2025-09-15
Diskette, Program Parameters	12002716	AA30135	N/A
CD-ROM, Program Parameters	12002715	BA30135	N/A

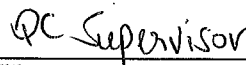
Universal Components	Material #
sample vials	12005138
thermal paper	220-0696

This is to certify that this product conforms to our specifications.

Each unit of whole blood used in the manufacture of this calibrator was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to HIV-1 and HIV-2, HIV antigen (p-24), and Hepatitis C (HCV). No test method can offer complete assurance that products containing human source materials will be absent of these and other infectious agents. In accordance with good laboratory practice, all human source material should be considered potentially infectious for Hepatitis B (HBV), Hepatitis C (HCV), HIV-1, HIV-2, HTLV-I, HTLV-II and all other infectious agents; therefore, handle calibrators and controls with the same precautions used with patient specimens.



 Signature



 Title

05/01/23

 Date