



CERTIFICATE OF ANALYSIS

STP Prime Plus Blood Gas/CO-Oximeter
Controls 1, 2, and 3
Lot Number 25322050

Ref Number 57844
Exp Date 2026-11-11
Date of Manufacture 2025-11-11
UDI# (01)00385480578448(11)251111(17)261111(10)25322050

Level 1 Lot 25315066

	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.180 - 7.230	Pass
pCO2 mmHg	55.0 - 65.0	Pass
pO2 mmHg	58.0 - 68.0	Pass
tHb g/dL	18.0 - 22.0	Pass
COHb %	25.0 - 33.0	Pass

Level 2 Lot 25317035

	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.350 - 7.420	Pass
pCO2 mmHg	39.0 - 45.0	Pass
pO2 mmHg	97.0 - 107.0	Pass
tHb g/dL	12.0 - 15.0	Pass
COHb %	18.0 - 24.0	Pass

Level 3 Lot 25318009

	<u>Spec</u>	<u>Pass/Fail</u>
pH	7.570 - 7.650	Pass
pCO2 mmHg	18.0 - 26.0	Pass
pO2 mmHg	135.0 - 149.0	Pass
tHb g/dL	5.0 - 8.0	Pass
COHb %	3.0 - 9.0	Pass

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials except Total Hemoglobin (THb) and MetHemoglobin (metHb) which are traceable by using Cyanmethemoglobin method.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector
Title

12/19/2025
Date