



**CERTIFICATE OF ANALYSIS**

STP Prime Plus Blood Gas/CO-Oximeter

Controls 1, 2, and 3

Lot Number 25196028

Ref Number 57844

Exp Date 2026-07-09

Date of Manufacture 2025-07-09

UDI# (01)00385480578448(11)250709(17)260709(10)25196028

Level 1 Lot

	<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

	<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

	<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

9/2/2025

Date