

**NOVA**<sup>®</sup>  
*biomedical*

## **CERTIFICATE OF COMPLETION**

*This is to certify that*

*Alexandru Grigoret*

*has successfully completed Stat Profile Prime Plus Service and Application  
Training.*

April 10-11, 2023

Date of Training

*Huseyin Dibekkaya*

Support Training Program Facilitator  
International Regional Support Manager

Chisinau / Moldova

Location of Training

**NOVA**<sup>®</sup>  
*biomedical*

## **CERTIFICATE OF COMPLETION**

*This is to certify that*

*Ion Negru*

*has successfully completed Stat Profile Prime Plus Service and Application  
Training.*

April 10-11, 2023

Date of Training



*Huseyin Dibekkaya*

Support Training Program Facilitator

International Regional Support Manager

**Chişinău / Moldova**

Location of Training

**NOVA**  
*biomedical*

**CERTIFICATE OF COMPLETION**

*This is to certify that*

*Sergiu Sorocovici*

*has successfully completed Stat Profile Prime Plus Service and Application  
Training.*

**April 10-11, 2023**

**Date of Training**

**Chişinău / Moldova**

**Location of Training**



**Huseyin Dibekkaya**

**Support Training Program Facilitator  
International Regional Support Manager**



## **CERTIFICATE OF COMPLETION**

*This is to certify that*

*Victor Meleca*

*has successfully completed Stat Profile Prime Plus Service and Application Training.*

**April 10-11, 2023**

Date of Training

**Chişinău / Moldova**

Location of Training

A blue ink signature of Huseyin Dibekkaya, consisting of a stylized, cursive script.

**Huseyin Dibekkaya**

Support Training Program Facilitator  
International Regional Support Manager

**NOVA**<sup>®</sup>  
*biomedical*

## **CERTIFICATE OF COMPLETION**

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Date of Training



*Huseyin Dibekkaya*

Support Training Program Facilitator

International Regional Support Manager

**Chişinău / Moldova**

Location of Training



Product Service

# Certificate

No. Q5 020747 0242 Rev. 00

**Holder of Certificate:** **Nova Biomedical Corporation**  
200 Prospect Street  
Waltham MA 02454  
USA

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Clinical Chemistry and Hematology (Co-Oximeter) Medical Devices including Near Patient / Point of Care Analyzers, Calibrators, Controls, Reagents, Sensors, Kits used in the Detection of Blood Analytes, Electrolytes, pH, Metabolites; Self Testing and Near Patient / Point of Care In-Vitro Diagnostic Devices for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid, including Meters, Test Strips and Controls; Self Testing In-Vitro Diagnostic Medical Devices for the Determination of the percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood, and Albumin and Creatinine in Urine including Analyzers, Test Cartridges and Controls; Contract Manufacturing of Electronic Medical Devices; Contract Manufacturing of Disposable Medical Devices; and Distribution of Lancets

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 00)

**Report No.:** 72166286

**Valid from:** 2021-10-29  
**Valid until:** 2024-10-28

**Date,** 2021-10-29

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 020747 0242 Rev. 00

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Nova Biomedical Corporation  
165 Lexington Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Meters  
for the Management of Diabetes Blood Glucose, Ketone,  
Cholesterol and Uric Acid.

Nova Biomedical Corporation  
39 Manning Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Test  
Strips for the Management of Diabetes Blood Glucose, Ketone,  
Cholesterol and Uric Acid.  
Distribution of Near Patient / Point of Care, and Self-Testing Test  
Strips, Meters and Controls. Distribution of Lancets.

Nova Biomedical Corporation  
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation,  
Servicing and Technical Support of In-Vitro Diagnostic Clinical  
Chemistry and Hematology (Co-Oximeter) Medical Devices  
including Near Patient / Point of Care Analyzers, Calibrators,  
Controls, Reagents, Sensors, Kits used in the Detection of Blood  
Analytes, Electrolytes, pH, Metabolites; Self Testing and Near  
Patient / Point of Care In-Vitro Diagnostic Devices for the  
Management of Diabetes Blood Glucose, Ketone, Cholesterol and  
Uric Acid, including Meters, Test Strips and Controls; Self Testing  
In-Vitro Diagnostic Medical Devices for the Determination of the  
percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density  
Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood,  
and Albumin and Creatinine in Urine including Analyzers, Test  
Cartridges and Controls; Contract Manufacturing of Electronic  
Medical Devices; Contract Manufacturing of Disposable Medical  
Devices

**NOVA**<sup>®</sup>  
*biomedical*

**CERTIFICATE OF COMPLETION**

*This is to certify that*

*Sergiu Sorocovici*

*has successfully completed Stat Profile Prime Plus Service and Application  
Training.*

**April 10-11, 2023**

**Date of Training**

**Chişinău / Moldova**

**Location of Training**



**Huseyin Dibekkaya**

**Support Training Program Facilitator  
International Regional Support Manager**



## PRIME PLUS / VET SHELF-LIFE & WARRANTY INFORMATION

REV: 07/2021

### Stat Profile® Prime Plus and Stat Profile Prime Plus VET



DESCRIPTION		WARRANTY	SHELF LIFE
<b>Sensors Cards</b>			
57820	Prime-Plus Sensor Card: w/ COOx (Standard)	14 Days/200 Samples*	12 Mos
57822	Prime-Plus Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58642	Prime-Plus Sensor Card: NO COOx (Standard)	14 Days/200 Samples*	12 Mos
58643	Prime-Plus Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
57821	Prime-Plus: Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58577	Prime-Plus VET- Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58578	Prime-Plus VET- Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
58581	Prime-Plus VET- Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58379	Prime-Plus Sensor Card- BLANK RENAL Sensor Card: (Clinical & VET)	Free of Defects	n/a
57823	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (CLINICAL)	Free of Defects	18 Mos
59345	Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (VET)	Free of Defects	18 Mos
<b>Calibrators</b>			
57825	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample	100 Samples or 35 Days	18 Mos
57826	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
57827	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample	300 Samples or 35 Days	18 Mos
57828	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample	400 Samples or 35 Days	18 Mos
57829	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
57831	Stat Profile Prime Plus® Calibrator Cartridge 100 Sample with Creat / BUN	100 Samples or 21 Days	18 Mos
57832	Stat Profile Prime Plus® Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
57833	Stat Profile Prime Plus® Calibrator Cartridge 300 Sample with Creat / BUN	300 Samples or 21 Days	18 Mos
57834	Stat Profile Prime Plus® Calibrator Cartridge 400 Sample with Creat / BUN	400 Samples or 21 Days	18 Mos
57835	Stat Profile Prime Plus® Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
58395	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
58396	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
58405	Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
58404	Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
<b>AQC Packs</b>			
57838	Stat Profile Prime Plus® Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
57839	Stat Profile Prime Plus® Auto QC Cartridge 320 Sample	320 Samples or 32 Days	18 Mos
57840	Stat Profile Prime Plus® Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
57841	Stat Profile Prime Plus® Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
57842	Stat Profile Prime Plus® Auto QC Cartridge 210 Sample with Creat / BUN	210 Samples or 21 Days	18 Mos
57843	Stat Profile Prime Plus® Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
58406	Stat Profile Prime Plus® VET Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
58407	Stat Profile Prime Plus® VET Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
58408	Stat Profile Prime Plus® VET Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
58409	Stat Profile Prime Plus® VET Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
57844	Stat Profile Prime Plus® Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57845	Stat Profile Prime Plus® Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

57812	Stat Profile Prime Plus® VET Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57813	Stat Profile Prime Plus® VET Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

**Miscellaneous:**

52669	Luer Station Safety Port (5/pack) (Prime/Prime-Plus)	Free of Defects
52582	Probe/S-Line Assy : Prime/Prime-Plus	Free of Defects
49200	Printer Paper (rolls: 5/pkg) (small-style)	Free of Defects

Electro-Mechanical Components & Assemblies

**\*Whichever comes first.**

**NOTE: THE WARRANTED USE EXPRESSED ABOVE IS ONLY VALID IF IT OCCURS**

**PRIOR TO THE "USE BEFORE DATE" LISTED ON THE PACKAGE LABEL.**