903 Neonatal Moldova Card
10535146 Rev.AB
Job # 7209721-001
04-16-21
First Proof

EBF

903 Neonatal Moldova Card

200 Cards per Pack **903™**

REF 10535146 Rev AB | 2026-04-30 | LOT 7209721 W201

1)Do not touch sample area **2)Do not use if damaged**

IVD

EASTERN
BUSINESS FORMS, INC.
530 Old Sulphur Springs Rd
Greenville, SC 29607 USA

(01) 00860802000383
(02) 200 (10) 7209721/W201
(17) 2026-04-30

White Thermal Transfer Label
with Permanent Adhesive
3" x 3" (76.2mm x 76.2mm)
Prints Reflex Blue, Red 185
and Black Thermal Ink

☒ Approved As Is

☐ Not Approved, Show Another Proof

Signature N. Usurelu

Date 03.05.2022

Digitally signed by Ceaicovschi Tudor
Date: 2022.11.15 16:23:59 EET
Reason: MoldSign Signature
Location: Moldova

Не дотрагивайтесь до области внутри кружков
Не используйте поврежденные тест-бланки

Кружки на бланке пропитывают равномерно, обильно и аккуратно, по одной капле крови на каждый кружок, взятой обычным способом из пятки. Капли могут быть больше чем кружки, но ни в коем случае меньше. Кровяные пятна высушиваются на воздухе.

Леч. учреждение

Ф.И.О. матери

пол:
☐Жен.
☐Муж.

Ф.И.О. ребенка

Дата рождения

Вес при рождении

Дата взятия пробы

Нормальная беременность ?
Недоношенный ?

Антибиотики ?
Сульфонамиды ?

Асфикция ?
Желтуха ?

Eastern Business Forms
530 Old Sulphur Springs Rd.
Greenville, SC 29607, USA

903™

2026-04-30

REF 10535146 Rev.AB

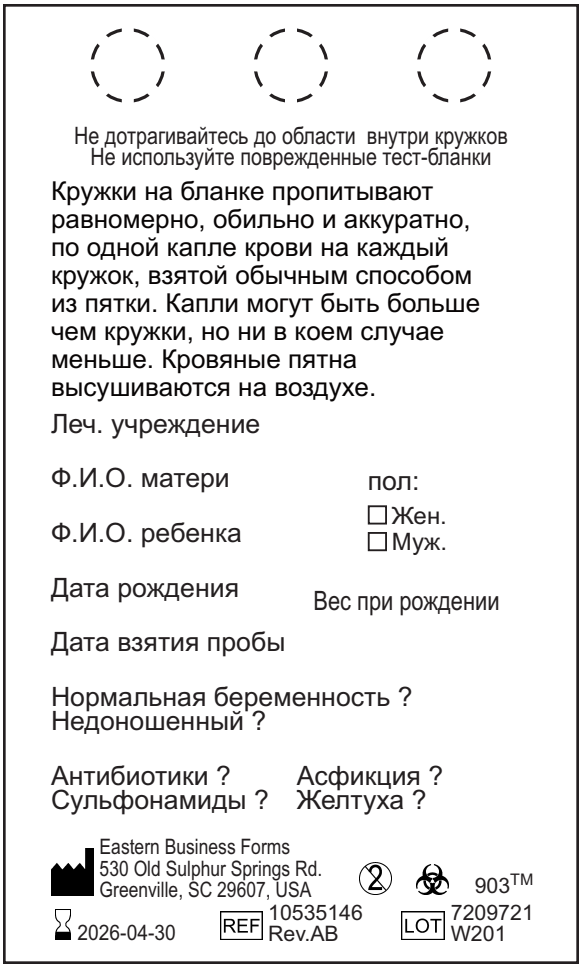
LOT 7209721 W201

Single Sheet 903 Lot W201
3" x 5" (±1/16") - 76.2mm x 127mm
Prints Bio Black 586 Ink
Circle size: 9mm ID

903 Neonatal Moldova Card
10535146 Rev.AB
Job # 7209721-002
04-26-21
Second Proof

CUSTOMER	
APPROVED ☒	
NOT APPROVED ☐	
SIGNATURE	N. Usurelu
NAME:	Dr. Natalia Usurelu
DATE:	03.05.2022
EBF	
REF: 10535146	REVISION: AB
DATE:	
SIGNATURE	

Note: This PDF form layout is produced to a 1:1 scale. All copy and construction features are shown in their proper position per your specifications. Production variances will result in a potential ± 1/16" (1.6mm) tolerance.



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Second Proof

CUSTOMER	
APPROVED ☐	
NOT APPROVED ☐	
SIGNATURE	
NAME:	
DATE:	
EBF	
REF: 10535146	REVISION: AB
DATE:	
SIGNATURE	

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Date

EU DECLARATION OF CONFORMITY

Manufacturer's Name and Address

Eastern Business Forms, LLC
530 Old Sulphur Springs Rd.
Greenville, SC 29607 USA

Declaration of Conformity

I, Richard Haines, as management's representative and the person responsible for regulatory compliance, and on behalf of EBF who has sole responsibility over issuance of this declaration of conformity, hereby declare that the below described product:

(i) Complies with all requirements of the Regulation EU 2017/746 for *In Vitro* Diagnostic Medical Devices (IVDR),
(ii) Has had its classification updated according to the IVDR classification rules, and
(iii) Conforms to requirements specified in Article 17 and Annex IV EU Declaration of Conformity, with further details as follows:

Registered (US FDA) Proprietary Name:	903 Filter Paper
International Trade Name – as it may appear on devices:	903™
Family/Model Name – as it may appear on Device, Pack Label, or Instructions For Use:	903™ Filter Paper, and/or other unique descriptive names as specified by customers.
Authorized Representative:	CMC Medical Devices & Drugs S.L. C/ Horacio Lengo N18, CP29006, Malaga, Spain +34951214054
Description:	903 Filter Paper (903FP) is an IVD specimen receptacle, customized to suit the dried blood spot (DBS) collection needs of clinical newborn screening (NBS) or adult/child (A/C) testing programs, or other customer specimen collection requirements.
Catalog, Article, Serial Numbers:	Catalog/Article Reference Number(s) are specific to each customer's 903FP device layout/artwork design in optional single- or multi-part, or cassette configurations. Product identification/traceability controlled by unique device identification (UDI); 903FP lot #, job order #, and S/N's which are optional per customer requirements.
Basic GS1/GUDID UDI-DI:	00850039198007 (representing devices made from 903 Filter Paper Lot # W211)
Risk-Based Classification & Rule:	Class A, Rule 5 (single-use, inactive, non-sterile, non-implantable, not self-testing)
GMDN Code:	45522, Blood Collection Paper

Quality Management System Certificate

Conformity Assessment Body Issuing the Certificate:	NQA 289 Great Road, Suite 105 Acton, MA 01720 USA
Standard:	ISO13485:2016
Certificate Number:	17633
Issuance Date:	12/6/2020
Expiry Date:	12/4/2023

Primary Standards Applied

EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 18113-1:2011	European Norm – In Vitro Diagnostic Medical Devices – Information Supplied by the Manufacturer (Labelling) – Part 1: Terms, Definitions and General Requirements
EN ISO 15223-1:2021	European Norm – Medical Devices – Symbols for Use with Medical Device Labels, Labelling and Information to be Supplied
CLSI NBS01-7E	Clinical & Laboratory Standards Institute – Blood Collection on Filter Paper for NBS Programs

Place and Date of Issue

Location / Date:	Name, Position and Signature of Responsible Person
Greenville, SC USA / 3/23/2022	R. Haines (on behalf of EBF Top Management) Quality/Regulatory Manager

Certificate of Registration

nqa global assurance

This is to certify that the Quality Management System of:

Eastern Business Forms, LLC

530 Old Sulphur Springs Rd.
Greenville SC 29607
United States of America

applicable to:

Manufacture, assembly and distribution of filter paper-based specimen receptacles and kits

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 13485:2016

Certificate Number:	17633
EAC Code:	07
Certified Since:	December 5, 2014
Valid Until:	December 4, 2023
Reissued:	December 6, 2020
Cycle Issued:	December 5, 2020

For and on behalf of NQA, USA

ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY