

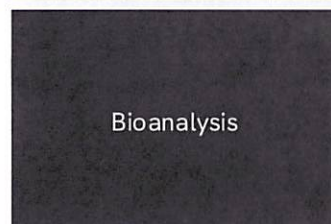
Stock Card Configurations



- Two Part Card
- Front printing only with Black Bio-Inert Ink
- 3/16" Arabic Press Number (serial number)
- Blood Collection Circles = 12.7mm ID
- Card Size: 4" (W) x 3" (H)



- Two Part Card
- Flap covers blood spots and tucks into the space between the demo and filter paper
- 2 Colors on 125# White Tag
- Code 3 of 9 Barcode with one human readable (serial number)
- Blood Collection Circles = 12.7mm ID



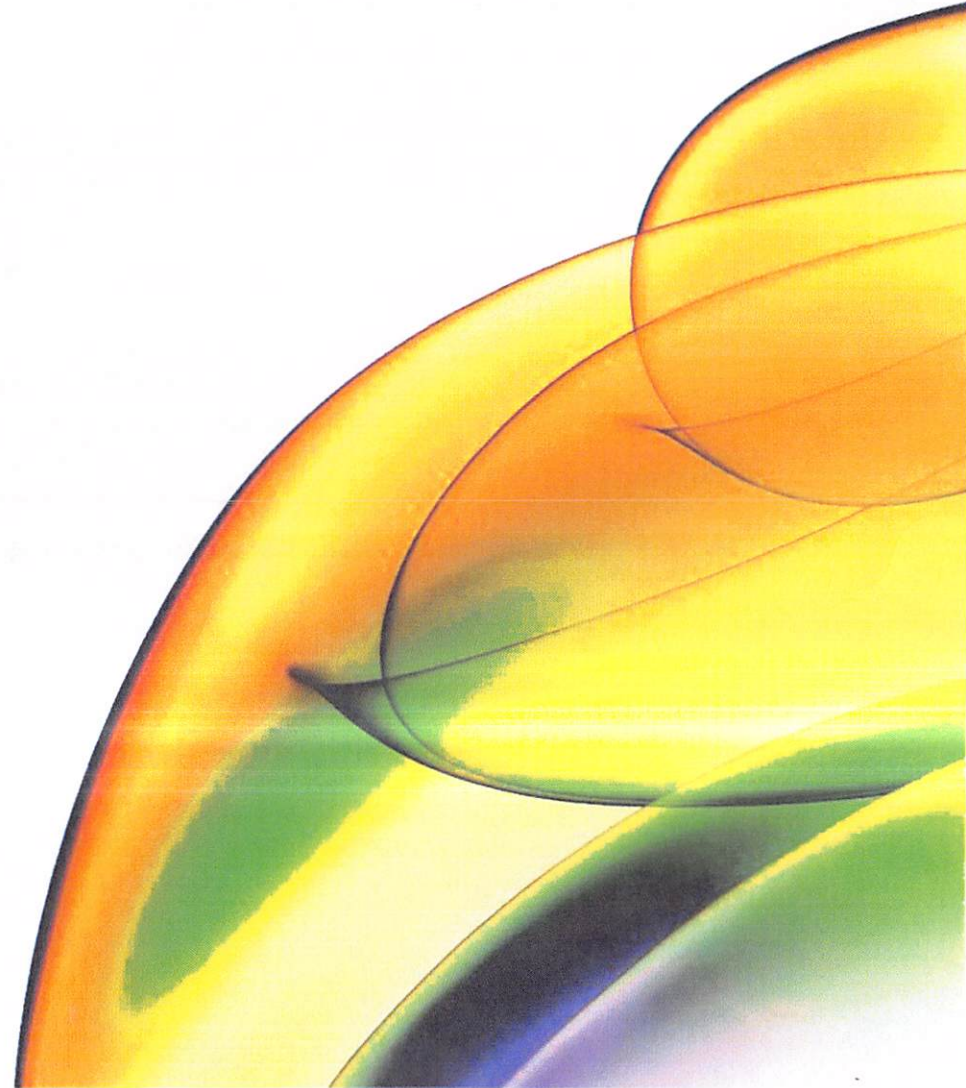
- Three Part Cassette
- Cassette Window dimensions: 61mm x 19mm
- 2 Colors on 125# White Tag
- Blood Collection Circles = 10mm OD
- Card Size: 3 1/3" (W) x 2 3/32" (H)

Revvity™ Stock Cards

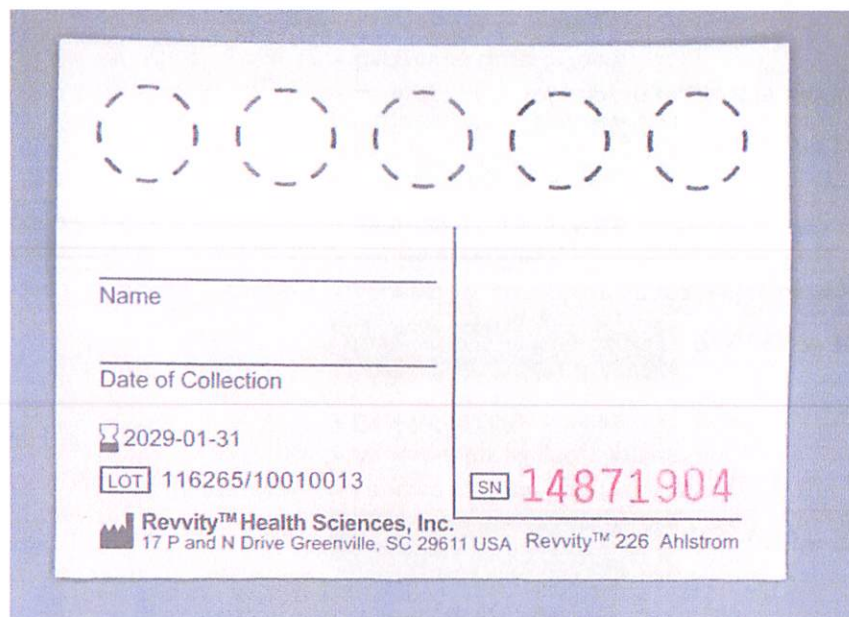
Manufactured in Greenville, South Carolina USA

revvity

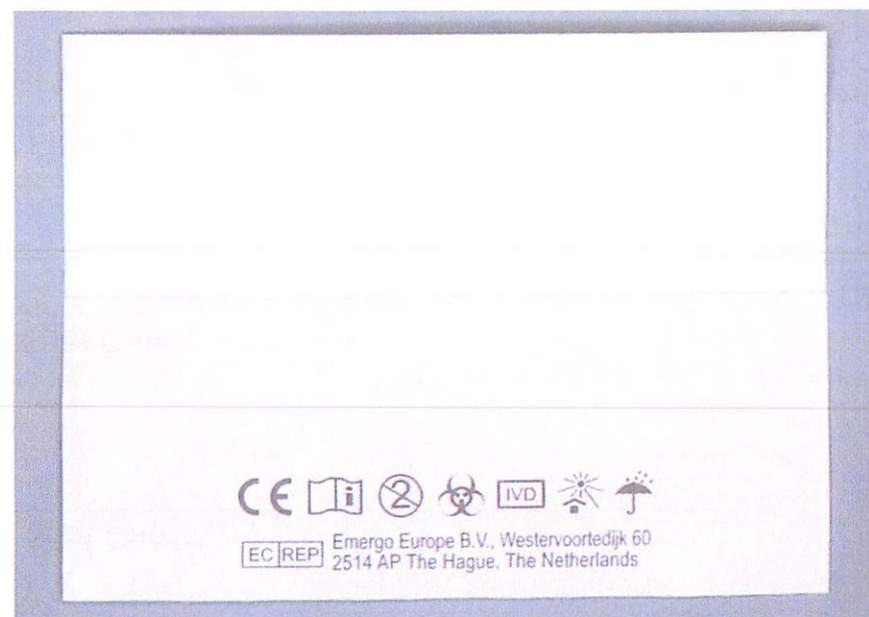
April, 2024



Five Spot Cards



The front of the card features five dashed circles at the top for blood collection. Below them are fields for 'Name' and 'Date of Collection'. A date stamp shows '2029-01-31'. A lot number '116265/10010013' and a serial number '14871904' are printed. The bottom section contains the Revvity Health Sciences, Inc. logo and address: '17 P and N Drive Greenville, SC 29611 USA' and 'Revvity™ 226 Ahlstrom'.



The back of the card displays regulatory and safety information. It includes CE, IVD, and biohazard symbols, along with a warning symbol. The text reads: 'Emergo Europe B.V., Westervoortdijk 60 2514 AP The Hague, The Netherlands'.

QTY per Pack =
100 Cards

Two Part Card
(Revvity™ 226 Filter Paper)

Blood Collection
Circles = 12.7mm ID

Five Spot Cards

GR2261001

Revvity™ IVD-EU Five Spot Card*

- Labeled for distribution in the European Union
- Expiration Date: 5 Years

GR2261002

Revvity™ RUO Five Spot Card**

- Labeled for Research Use Only
- Available for all geographies
- Expiration Date: 5 Years

GR2261006

Revvity™ NBS Five Spot Card*

- Labeled for distribution in the United States
- For NBS use ONLY
- Expiration Date: 5 Years

GR2261008

Revvity™ IVD-ROW Five Spot Card*

- Labeled for distribution in the Rest of World
- Expiration Date: 5 Years

Spot Saver Cards



QTY per Pack =
100 Cards

Two Part Card



Blood Collection
Circles = 12.7mm ID

Spot Saver Cards

GR2261003

Revvity™ IVD-EU Spot Saver Card*

- Labeled for distribution in the European Union
- Expiration Date: 5 Years

GR2261005

Revvity™ RUO Spot Saver Card**

- Labeled for Research Use Only
- Available for all geographies
- Expiration Date: 5 Years

GR2261007

Revvity™ NBS Spot Saver Card*

- Labeled for distribution in the United States
- For NBS use ONLY
- Expiration Date: 5 Years

GR2261009

Revvity™ IVD-ROW Spot Saver Card*

- Labeled for distribution in the Rest of World
- Not Sellable in Argentina, Brazil, China & Mexico
- Expiration Date: 5 Years

GRNK1102

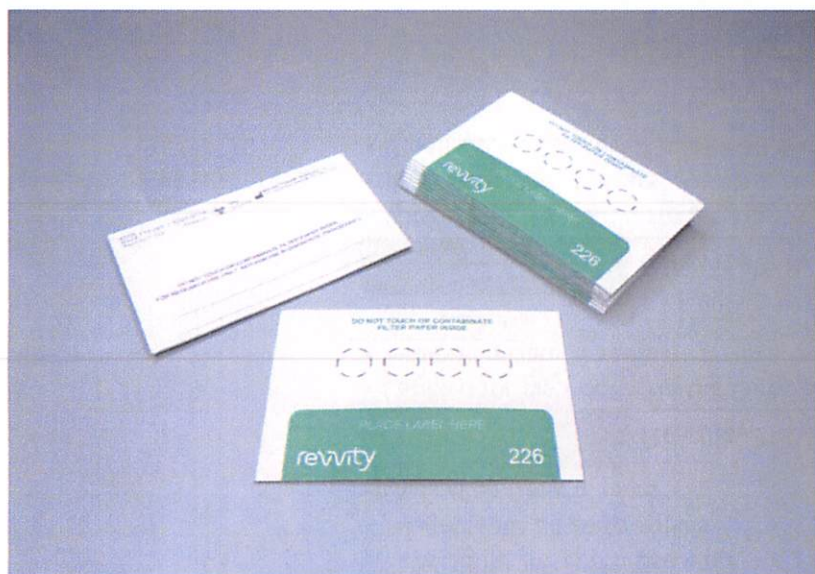
Revvity™ IVD-US Spot Saver Card*

- Labeled for distribution in the United States
- NOT for NBS use
- Expiration Date: 5 years



*Products may not be licensed in accordance with the laws in all countries, such as the United States and Canada. Please check with your local representative for availability. **For Research Use Only. Not for use in diagnostic procedures.

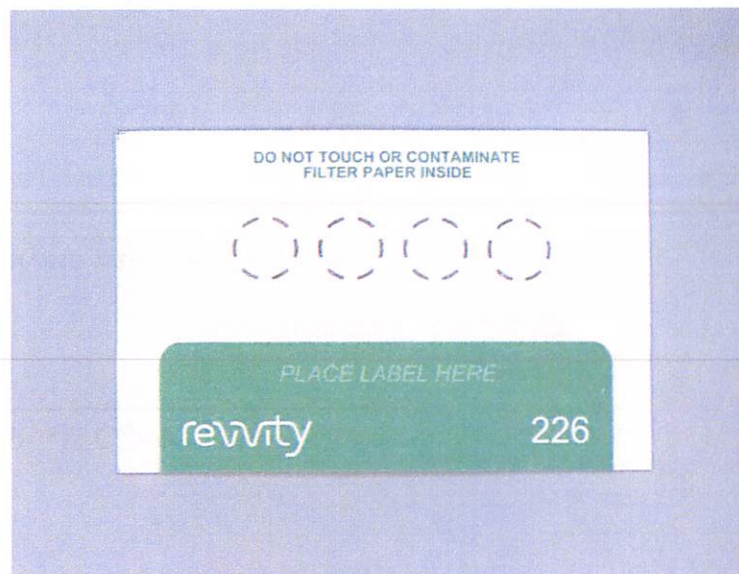
Bioanalysis Cards



QTY per Pack =
100 Cards

Three Part Cassette

Blood Collection
Circles = 10mm OD



Compatible with Panthera-Puncher™ 9 & DBS Puncher

Bioanalysis Cards

GR2261004 Revvity™ Bioanalysis Card**

- Labeled for Research Use Only
- Available for all geographies
- Expiration Date: 5 Years

GR2261010 Revvity™ IVD-EU Bioanalysis Card*

- Labeled for distribution in the European Union
- Expiration Date: 5 Years

GR2261011 Revvity™ IVD-EU Bioanalysis Perf Circle Card*

- Labeled for distribution in the European Union
- Expiration Date: 5 Years
- Blood Collection Perf Circles = 11.5 mm OD



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Custom cards

Pennsylvania Department of Health
 Bureau of Epidemiology
 Phone: (717) 785-6462 • TTY: (717) 785-6514

TOP COPY FOR LAB, SUBMITTER MAY KEEP YELLOW COPY

PA220945801

EXPIRES 2026-10-31

GIVE TO PARENT / LEGAL GUARDIAN

FOLD BACK DURING DRYING BUT DO NOT REMOVE THIS COVER FLAP. IT IS FOR THE PROTECTION OF THE SPECIMEN HANDLERS.

PLEASE MAKE SURE THAT THE BLOOD SPOTS ARE COMPLETELY DRY

AND PROTECTIVE FLAP IS IN PLACE BEFORE SUBMITTING SPECIMEN

BIOHAZARD

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BIOHAZARD

Wales Newborn Bloodspot Screening Test

Expiry Date 2028-12

DO NOT TOUCH SAMPLE AREA. Do not use if damaged.

Wales Newborn Bloodspot Screening Test

Expiry Date 2028-12

DO NOT TOUCH SAMPLE AREA. Do not use if damaged.

Desired patient information

Indications for Use

The Revvity™ GRNK1 Cards are intended to be used as a medium to collect and transport whole blood specimen spots to a laboratory.

Device Description

The Revvity™ GRNK1 Card provides a uniform surface for the collection of blood spots. The Revvity™ GRNK1 Card incorporates the Ahlstrom 226 filter paper.

Basis weight: 110lb +/- 5% per ream

pH: 5.7 – 7.5

Ash %: 0.1% maximum

Warnings and Precautions

For In Vitro Diagnostic Use.

To prevent specimen contamination, do not touch any of the filter paper circles before or after blood collection. All blood should be treated as potentially infectious material and precautions should be practiced at all times to minimize exposure. Once blood is applied, handle collection card as biohazardous.

Limit the number of lots in use at any one time. It is important that all demographic information on the device is filled out accurately and completely.

Do not use after expiration date printed on each card.

Cards are not designed to be modified. If card(s) is found to be defective, contact Revvity™ Health Sciences' sales department for instructions on the return of the card(s) and or destruction, if necessary.

Storage Conditions (unused cards)

Store cards in a cool, dry location out of direct sunlight until ready for use. Cards should be stored in their original wrapping and stacked in a manner that avoids compressing the filter paper. Compression of the filter paper will alter its performance characteristics.

Specimen Collection and Handling

Proper collection and handling of blood spots is essential to obtaining reliable test results.

BLOOD SAMPLE COLLECTION INSTRUCTIONS

1. Clean fingertip with alcohol wipe. Let hand hang down for 15-20 seconds to stimulate blood flow.
2. Perform puncture using lancet device. Place palm facing upward on hard surface and with lancet press down on finger to puncture site.
3. Spot one blood drop on each circle, filling completely. Apply blood within circles, one side only. Do not allow finger to touch the sample application area, do not layer blood drops.

DRYING COLLECTED BLOOD SPOTS

1. Allow blood specimen to air dry horizontally at ambient temperature of 18° to 25° C (64° to 77° F), on nonabsorbent open surface for minimum 3 hours.
2. Do not touch the blood spots while drying. Keep protective flap open while drying.
3. Do NOT place test strips in front of air vents, use hair dryers, or other sources of moving air.
4. Store in cool place until shipping (avoid heat and direct sunlight).
5. Do not stack.

When shipping completed cards, make sure that the blood spots are completely dry, and the protective flap (where applicable) covers the dried blood spots. Submit the completed cards to the testing laboratory within 24 hours of collection.

Performance Characteristics

Blood Spot Absorption Time of 100µL: 5 – 30 seconds

Dried Blood Spot Diameter: 15 – 17mm

Labeling Symbols and Descriptions



Biological Risks



Batch code



Use by YYYY-MM-DD



In vitro diagnostic medical device



Manufacturer



Keep dry



Do not reuse



Catalogue number



Consult instructions for use



Keep away from sunlight



Serial Number



Revvity™ Health Sciences, Inc. • 00 +1.866.757.8334
17 P&N Drive, Greenville, SC 29611
Made in the USA



Certificate of Analysis

17 P & N Drive
Greenville, SC 29611

Phone: 00+1.864.537.5151

Toll Free: 866.757.8334 or
00+1.866.757.8334

Monday, December 9, 2024

Mosaic Diagnostics
A81327 ADRIANNEALLEN
9221 Quivira Rd
Overland Park, KS 66215-3905

Attn: Susan Fisher | 724-617-2326

This document hereby certifies that Revvity™ Health Sciences, Inc. is registered with the FDA and complies with the FDA's regulations FDA 21CFR820. All the proper steps were taken to prevent contamination during the manufacturing process of this job. The QC samples, pulled based on a Sampling Plan that is compliant with ANSI ASQC Z1.4 Standards. In addition, we have visually verified that all copy and specifications agree with the approved design layout and the purchase order received.

Product Description: PerkinElmer GRNK1 Device for the Collection of Human Blood Spots
Device Name & Item # (if applicable): GRNK110220006 PKI IVD US Spot Saver Card
Customer's PO #: DR9540371
Job #: 5097354
Grade 226 Filter Paper Lot #: 116265
Device Expiration Date: 2029-02-28
Date of Manufacture: 2024-04-04
Total Quantity Ordered: 45 [100/pk]

SHIPMENT INFORMATION

Shipment	Date Shipped	Starting Number	Ending Number	Quantity Printed	Quantity QC Samples	Qty Missing Numbers	Quantity Per Pack	Total Quantity Shipped
4988081	12/9/2024	NA	NA	45	NA	NA	100	45
Totals (to date)				45				45

BLOOD SPOT TESTING DATA

Shipment	Average Absorption Time (seconds)	Average Diameter (millimeters)
Complete Job	9.13	16.25
Averages (to date)	9.13	16.25

This CoA ☒ does indicate the completion of the job.
☐ does not indicate the completion of the job.

Sincerely,
Kerry Chunko
Kerry Chunko
Sr. Quality Manager



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