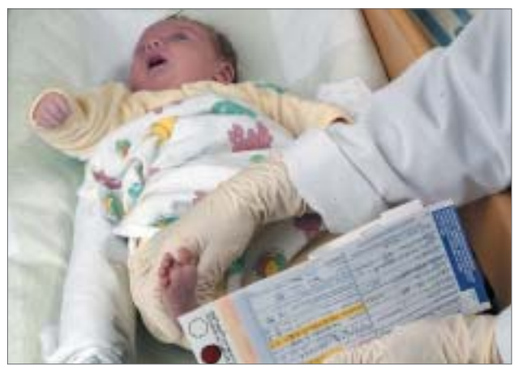
Neonatal Screening Products:
Originally used to test for phenylketonuria (PKU) these cards now screen for more than 30 potential diseases. Simple. Accurate. Effective. Lifesaving.

Neonatal Screening

Whatman offers a line of products for neonatal and population screening. These products are used in physician's offices, home blood sample collection kits and in methods for sample archiving.

Specimen collection papers allow researchers to collect samples for analysis from a wide range of sources. Samples can be collected in a controlled laboratory environment or in more challenging field environments.

It is important that the paper selected for specimen collection is extremely pure and consistent and has excellent absorption characteristics.



Neonatal Screening

903® Specimen Collection Paper

For Body Fluid Sample Collection and Transport

Since Dr. Robert Guthrie first published procedures for screening newborns for phenylketonuria (PKU), the 903 specimen collection paper has been the international standard for body fluid sample collection, transport, analysis and archiving.

The 903 paper, an FDA-registered *in vitro* Class II medical device, is used in virtually all US newborn screening programs and in most newborn screening programs throughout the world. Widespread testing for phenylketonuria (PKU) has led to early detection and intervention for tens of thousands of babies worldwide. Newborn screening programs today screen for, depending on the state or country, anywhere from three to eleven or more analytes, including congenital hypothyroidism, galactosemia, branched-chain ketonuria, maple sugar urine disorder and sickle-cell anemia. More recently, with the advent of tandem mass spectrometry technology, many programs are adding less frequently occurring disorders to their panel of analytes, including MCAD, cystic fibrosis and a range of amino acid disorders.

Guaranteed Consistency

Whatman maintains statistical process control (SPC) over the manufacture of 903 specimen collection paper. State-of-the-art equipment ensures uniformity and adherence to specified parameter ranges. Since the stability of the collected sample can be affected by the composition of the paper, Whatman carefully controls the manufacturing process to ensure consistent composition, uniform thickness, flow-rate, absorbency and purity.

Manufacturing Quality Assurance

The 903 paper is manufactured from 100% pure cotton linters with no wet-strength additives. Whatman guarantees to the newborn screening community that each lot of paper that is manufactured will last for at least 12 months at current usage levels.

Since it is a medical device, 903 paper is manufactured and tested according to FDA Quality System Regulations and must meet a performance standard. The critical parameters, as defined in the CLSI consensus standard for newborn screening sample collection, are blood absorbency, serum uptake and circle size for a specified volume of blood.

Whatman Quality Assurance tests 903 paper for blood absorbency and circle size throughout the manufacturing run. In addition, the same tests, plus serum uptake, are also conducted for each lot of 903 paper by an independent testing laboratory and by the Centers for Disease Control Newborn Screening Quality Assurance Program. Only when all test results confirm that a lot of 903 paper meets the CLSI specifications is that lot released for use for specimen collection.

Post-printing Quality Assurance

For most applications, the 903 paper is printed and provided as part of a form that includes detailed demographic information about the patient being tested. The process for the printing of specimen collection paper to be used for neonatal screening is strictly defined in the NCCLS standard. Improper printing can calender or crush the paper, negatively impacting its absorption characteristics. This can result in unacceptably long absorption times, 'layering' of blood spots and incomplete absorption. Because of this, Whatman Quality Assurance tests a random sampling of forms from all printed collection form lots for blood absorption time, circle size and caliper. A certificate of analysis is available upon request for each lot of printed blood collection forms.

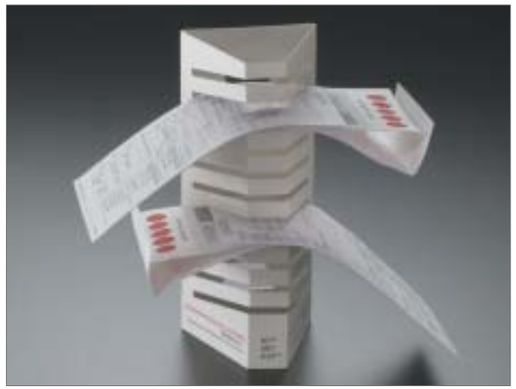
Beyond Neonatal Testing

While initially used for newborn screening from dried blood spots (DBS), 903 paper is now also widely used for the collection of many types of samples, including collection of blood samples for HIV, HCV and glycated hemoglobin A1c testing. In addition, there are a number of tests that incorporate 903 paper for physician's office collection of samples that are then sent to a central laboratory for analysis, e.g., blood lead-level monitoring. The 903 paper is an ideal medium on which to collect samples for epidemiological studies.

Dry Rak for Collection Card Drying

The Whatman Dry Rak is designed to accommodate multiple collection forms at one time, safely and properly air-drying the blood specimens in a suspended horizontal position (CLSI Document LA4-A3, vol. 17 No. 16). The Dry Rak is easily assembled and can be affixed to a wall or counter top with optional velcro stickers.

Whatman offers a variety of generic collection cards that meet the requirements for many sampling programs.



Dry Rak

903 Multiple-part Neonatal Card

The multiple-part neonatal card includes a demographic portion in duplicate where information about the newborn, parents, physician and care can be entered. Each card has a unique sequential number and bar code. The tipped-on 903 collection paper is imprinted with five half-inch circles and has a wrap-around cover to protect the 903 paper before and after sample collection. Each circle holds 75-80 µL of blood.

903 Protein Saver Card

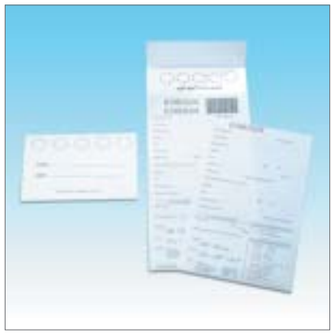
The sample collection area of the 903 Protein Saver Card contains five half-inch circles. Each circle holds 75-80 µL of sample. Wrap-around cover has spaces for name and date of collection and is imprinted with the universal biohazard symbol in conformance with USPS regulations. It carries the CE mark for the European Union and fits into Whatman foil barrier ziplock bags for storage.

903 Protein Saver Snap-apart Card

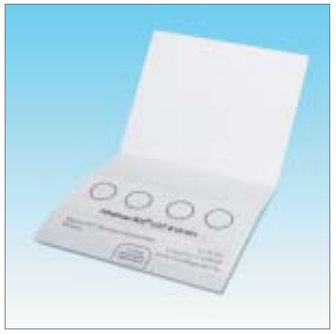
The 903 paper in this device, imprinted with four half-inch circles, is enclosed between two pieces of cover stock. Each circle holds 75-80 µL of sample. To use, one cover is snapped off, the sample is collected and the remaining cover is folded over the sample. This cover is imprinted with the universal biohazard symbol in conformance with USPS regulations.

Regulation Disclaimer - CE mark

Under regulations that went into effect in December 2003, specimen collection cards, including neonatal screening cards, which are to be used for human diagnostic tests, are classified as 'other' IVD devices under the European IVD Directive and require the CE mark if sold within the European Union. All 903 specimen collection devices manufactured and printed by Whatman for human diagnostic testing in the EU undergo post-printing quality control and carry the CE mark. Whatman will assume no responsibility for the quality or performance of 903 collection devices converted, printed or packaged by third party suppliers.



Multiple-part Neonatal Card



903 Protein Saver Card

Protein Saver Snap-apart Card

Training Materials

Educational materials illustrating the proper method for collecting neonatal samples are available from Whatman in six languages: English, German, French, Italian, Spanish and Brazilian Portuguese. Please contact our Technical Support for more information.

Ordering Information - 903 Specimen Collection Paper

Description	Quantity/Pack	Catalog Number
903 Multiple-part Neonatal Card	100	10 537 279
903 Protein Saver Card (EU)	100	10 531 018
903 Protein Saver Card	100	10 534 612
903 Protein Saver Snap-apart Card	100	10 534 320
Desiccant Packs	100	10 548 234
Foil-barrier Ziplock Bags	100	10 534 321
Plastic Ziploc Storage Bags 4" x 6"	100	10 548 232
Glassine Envelopes 3 ¼" x 4 ⅞"	100	10 548 236
Biohazard Labels ⅞" x ⅞"	1000	10 534 150
Dry Rak (with Velcro)	10	10 539 521
Dry Rak (without Velcro)	10	10 537 173
Hand Punch 3.1 mm	1	10 495 010

Specimen Collection Devices

Custom Printing

Whatman offers customized collection devices for use in large sampling studies. Specimen collection papers enable researchers and clinicians to obtain samples for analysis from a wide range of sources.

Regardless of where a sample is collected, information about the sample must be recorded and cataloged for each sample. Whatman custom printed forms are designed with this function in mind.

Whatman can develop individually designed collection matrices which can be used as a single-part form or incorporated into multiple-part specimen collection forms.

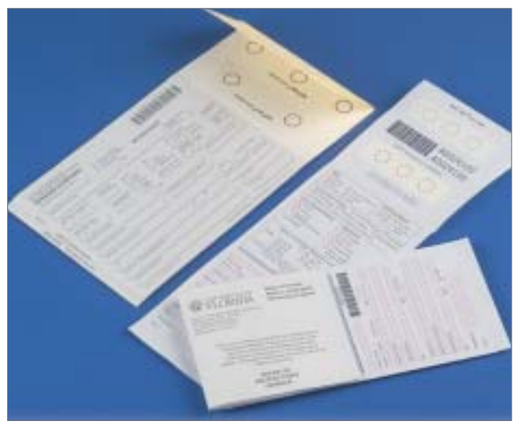
Customized Collection Devices

Custom Collection Device Options

Sequential Numbering
Forms can be provided with sequential numbering for tracking and identification.

Cassette Format
Custom cassette formats are ideally suited for automated processing.

Dual Paper Specimen Collection Cards
With increasing frequency, newborn screening programs and diagnostics companies are doing both protein-based and molecular testing from the same blood spots, often in different laboratories. To assist in this process, Whatman has developed a variety of sample collection card designs that incorporate two pieces of filter paper, one sheet of FTA and one sheet of 903, or two sheets of 903. In order to ensure accuracy of identification, the papers can be bar-coded.

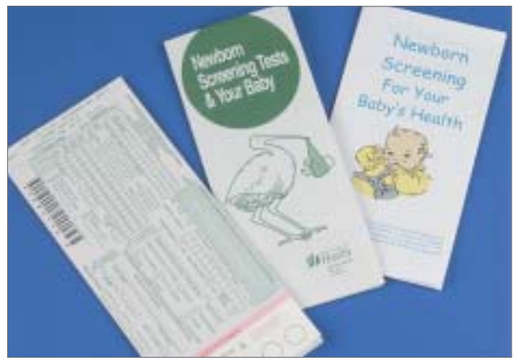


Specimen Collection Forms

Bar Codes
Forms can be provided with bar-coding on the demographic portion of the form and/or directly on the specimen collection paper in any bar code format that can print alpha-numeric characters (letters, digits and some special symbols). Data integrity is fortified by the use of modulus check digit characters.

OCR-scannable Format
Whatman can use special inks for printing forms that are invisible to optical character recognition (OCR) scanners, ensuring that scanners will detect only the variable demographic information.

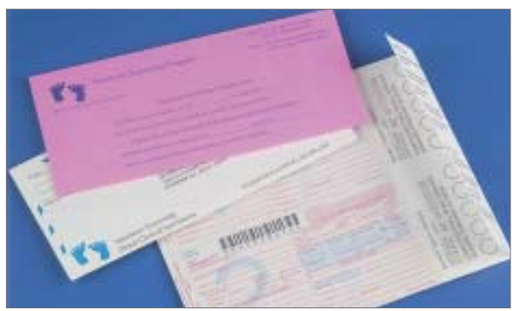
Parent Information Sheets/Pamphlets
Parent information sheets that are part of the neonatal collection device and include the device numbers can be provided as the first part of a multiple-part form. Alternatively, detailed parent information pamphlets can be glued to the form.



Parent Information Pamphlets

Transfer or Mailing Envelopes
Whatman can provide custom envelopes for mailing of samples to the central laboratory, for sending a screening form home with the parent for follow-up sampling, or sending samples to separate laboratories for non-standard screening tests, e.g. for DNA testing or supplemental screening. These envelopes are frequently color-coded.

Hearing Section
It is possible to add a section to a form for hearing test results. This puts all the screening results together in a database under a single control number.



Envelopes

Tip-ons
This is an economical alternative to using a full sheet of collection paper. Whatman can tip a small piece of 903 filter paper onto the end of a form, minimizing costs while ensuring high-quality results.

Color Coding
Custom printed forms can be color-coded to simplify form distribution before and after sample collection and to readily identify samples that require non-standard or supplemental testing.

Colored Inks and Papers
Forms can be printed in colored inks and/or screen tints as well as your choice of colored papers.

Multiple-part Forms
Printing of up to 8-part forms offers convenience and maintains integrity of information on all parts.

Wrap-around Covers
Offering a variety of wrap-around covers to ensure long-term sample integrity. Some of the options include 28-pound paper, translucent glassine or clear moisture-proof barrier.

Custom Packaging
A specified coding system can be printed on every package, carton and shipping box. Outside cartons can be labeled to reflect the sequential numbering of the forms enclosed.

Snap-apart Format
903 Specimen collection paper is protected prior to use. After sample application, the cover folds over and tucks into the flap in ‘matchbook’ fashion.

All customized specimen collection devices and 903 Neonatal Screening Cards now carry the CE Mark in the European Union.