510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k062932

B. Purpose for Submission:

New device

C. Measurand:

Not applicable (device is intended to be used to collect whole blood)

D. Type of Test:

Not applicable

E. Applicant:

Ahlstrom Filtration LLC

F. Proprietary and Established Names:

Ahlstrom 226 Specimen Collection Paper

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1675

2. Classification:

   Class II

3. Product code:

   JKA

4. Panel:

   75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):
   Ahlstrom 226 specimen collection paper is intended to be used as a medium to collect and transport blood specimen spots to a laboratory. The 226 paper will be in the format of a printed card that may be incorporated along with a tear-apart form for demographic information.

2. Indication(s) for use:
   Refer to Intended Use above.

3. Special conditions for use statement(s):

Prescription use only.

4. Special instrument requirements:
   Not applicable.

I. Device Description:

Ahlstrom 226 Specimen Collection Paper is made from 100% pure cotton linters and provides a uniform surface for the collection of blood spots. A drop of blood is applied to the filter paper and allowed to soak through the paper. The sample is then air dried and sent to a laboratory for analysis.

J. Substantial Equivalence Information:

1. Predicate device name:

   Whatman Body Fluid Collection Paper

2. Predicate K number(s):

   k932661

3. Comparison with predicate:

Item	Device	Predicate
Intended Use	Intended to be used as a medium to collect and transport blood specimen spots to a laboratory for further testing	Same
Matrix	Whole blood	Same
Storage conditions for unused cards	Store in a cool dry space away from direct sunlight.	Same
Specimen drying time	3 – 4 hours	3 hours minimum
Standard referenced	NCCLS/CLSI LA4 – A3: Blood Collection on Filter Paper for Newborn Screening Programs	Same

K. Standard/Guidance Document Referenced (if applicable):

NCCLS/CLSI LA4-A3: Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Third Edition

L. Test Principle:

Not applicable (device may be used to collect whole blood).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not applicable

   b. Linearity/assay reportable range:

   Not applicable

   c. Traceability, Stability, Expected values (controls, calibrators, or methods):

   Not applicable

   d. Detection limit:

   Not applicable

   e. Analytical specificity:

   Not applicable

   f. Assay cut-off:

   Not applicable

2. Comparison studies:

   a. Method comparison with predicate device:

   Not applicable

   b. Matrix comparison:

   Not applicable. This device is intended for the collection of whole blood only.

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable

   b. Clinical specificity:

   Not applicable

   c. Other clinical supportive data (when a. and b. are not applicable):

   The FDA recognized consensus standard for this device is NCCLS/CLSI LA4-A3: Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Third Edition. This standard describes four physical

properties of the filter paper and acceptance criteria for each:

1. **Absorption capacity** as measured by serum retention volume of a 1/8 inch paper punch taken from a dried blood spot. A range of 1.37 – 1.71 µL is considered acceptable.

Ahlstrom Lot 1 mean	1.477 µL
Ahlstrom Lot 2 mean	1.443 µL

2. **Homogeneity** of the filter paper lot (spot-to-spot and sheet-to-sheet variability). To perform this test, blood samples tagged with ^{125}I labeled T4 are applied to the filter paper. Samples (punches) of the filter paper are removed from pre-defined areas within the same lot and between lots. By measuring the amount of ^{125}I labeled T4, the homogeneity of the lot is calculated using a hierarchical, nested analysis-of-variance technique. An F-test is used to test equivalence of the mean values of the lots of paper. A p value of greater than 0.05 is considered acceptable.

Ahlstrom Lot 1	$p = 0.937$
Ahlstrom Lot 2	$p = 0.607$

3. **Diameter** of the circle for the dried blood aliquot. A range of 15 – 17 mm left to right and top to bottom is considered acceptable.

Ahlstrom Lot 1 mean	15.98 mm
Ahlstrom Lot 2 mean	16.75 mm

4. **Absorption time** for a 100 µL blood aliquot. A range of 5 – 30 seconds is considered acceptable.

Ahlstrom Lot 1 mean	7.88 seconds
Ahlstrom Lot 2 mean	12.74 seconds

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.