

**SPECIFICATION
FOR
BRIEFS, INCONTINENT, ADULT**

(This specification is released for procurement purposes until revised or rescinded)

SCOPE

This specification covers the requirements for adult incontinent briefs.

I. APPLICABLE STANDARDS

The following documents of issue in effect on the date of the Invitation For Bids shall form a part of this specification:

Federal Regulation 16CFR Parts 1610 and 1611

Total Capacity Test - ISO Test Method 11948-1:1996 – Urine-Absorbing Aids –
Whole Product Testing

The Rewet Test referenced herein Section III. A has replaced the previous Shuster Test Method TM-223C - Rewet Test for Briefs and Underpads.

Shuster Test Method TM-298 - Wetness Indicator Test for Briefs has been deleted.
Shuster Test Method TM-299 – Tab Refastenability Test for Briefs.

International Organization for Standardization (ISO); Reference <http://www.iso.org/iso/home.htm>
Reference for ordering standards: <http://www.iso.org/iso/store.htm>

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II. CLASSIFICATION

Category A - Super Performance

Type 1 – Briefs **MUST HAVE BOTH**, Breathable Side Panels and Polymer Hook Fasteners⁽¹⁾

Type 2 – Briefs **MUST NOT HAVE BOTH**, Breathable Side Panels and Polymer Hook Fasteners

Category B – High Performance

Type 1 - Briefs **MUST HAVE BOTH**, Breathable Side Panels and Polymer Hook Fasteners⁽¹⁾

Type 2 – Briefs **MUST NOT HAVE BOTH**, Breathable Side Panels and Polymer Hook Fasteners

Category C – Standard Performance

Type 1 - Briefs **MUST HAVE** Polymer Hook Fasteners **ONLY**

Size Requirements (Minimum each series): Medium, Large, and Extra Large.

⁽¹⁾ Refer to the Section III.B for definitions of breathable side panels and polymer hook fasteners.

III. REQUIREMENTS

A. Product Performance Requirements

Each brief shall be compliant to the Rewet, Rate of Acquisition and Total Capacity performance requirements outlined in Table 1. Rewet values indicated herein are maximum allowable and are shown in grams. The Total Capacity values indicated herein are minimum allowable and are shown in grams. Rate of Acquisition values indicated herein are maximum allowable and are shown in seconds.

Table 1 – Brief Category Performance Criteria

Categories	Super Performance Briefs ⁽¹⁾			High Performance Briefs ⁽¹⁾			Standard Performance Briefs ⁽¹⁾		
Sizes ⁽²⁾	Medium	Large	Extra Large	Medium	Large	Extra Large	Medium	Large	Extra Large
Rewet	≤ 0.15 grams			≤ 0.5 grams			≤ 2.0 grams		
ROA	≤ 70 seconds			≤ 85 seconds			≤ 100 seconds		
Total Capacity	≥ 1,600 grams	≥ 1,800 grams	≥ 2,000 grams	≥ 1,400 grams	≥ 1,600 grams	≥ 1,800 grams	≥ 1,200 grams	≥ 1,400 grams	≥ 1,600 grams
⁽¹⁾ Products need to comply with each of the three performance standards. No tolerance is allowed. ⁽²⁾ Actual waist range for each size brief shall be defined by the manufacturer's published data which may allow limited variation per size that is standard for the industry. Brief sizes from medium to extra large shall fit all the waist measurements from 34 inches to 63 inches.									

B. Construction Requirements

1. Briefs of either category or type require side panels for securement of the brief.
2. Type 1 briefs for both Categories A and B, must have breathable side panels that are constructed of apertured film or nonwoven fabric that allow air and water vapor to pass through the material.
3. Type 1 briefs for both Categories A and B must have only polymer hook type fasteners for the securement of the brief. Polymer hook fasteners are similar to the generic hook and loop fasteners except the exterior surface of the brief provides the integral loop material for the fastener.
4. Type 2 briefs for both Categories A and B allow all combinations of breathable side panels and polymer hook type fasteners not covered by Type 1, including the use of non-breathable side panels and tape tab fasteners.
5. The brief shall be "hourglass" shaped (leg cut-outs in topsheet, backsheet, and core).
6. The absorbent core shall consist of cellulose fiber and absorbent polymer, and shall be contoured (shaped in the crotch area) for good leg fit.
7. The backsheet shall be moisture impervious.
8. The topsheet for the briefs shall resist moisture return to the skin, and shall be constructed of polyethylene, polypropylene or polyester, either in apertured film form or nonwoven fabric form.
9. The brief shall have elastic leg gathers, each of which shall consist of at least three (3) strands.
10. The brief shall have a minimum of four (4) refastenable adhesive tapes or polymer hook type fasteners.
11. Reusable fasteners including adhesive strips and polymer hook types shall secure the brief and be readily unfastened without damage to the brief or to the fastener. Fasteners integrally attached to the brief shall not loosen or disconnect from the brief during use.
12. The brief shall have color and the product packaging shall have other affixed coding for convenient identification of size.

13. The brief shall have a readily visible wetness indicator.
14. The brief shall contain an odor counteractant or shall encapsulate a void to significantly reduce odor.
15. Adhesives and glues used in constructing the brief shall be water-insoluble, and will form continuous seals at the ends of the absorbent core to minimize leakage.
16. The absorbent material shall not migrate, compact, clump into a hard mass or separate upon encapsulating a fluid in the brief.
17. All materials used in the brief shall be safe for skin contact, and shall be harmless if ingested in small quantities.
18. A minimum of three (3) sizes (Medium, and Large & Extra Large) shall be provided for each category and type brief.
19. Each brief shall conform to all the performance requirements of SECTION III.A, Table 1.

IV. TESTS EVALUATION AND QUALITY ASSURANCE

A. Testing Requirements

Briefs are classified into the appropriate performance category based on results submitted by an independent laboratory for the following qualifying tests.

1. Total Absorbent Capacity: ISO Test Method 11948-1:1996. Protocol for this test may be purchased from the ISO (International Organization for Standardization) or from ANSI (American National Standards Institute).
2. Rate of Acquisition Test (ROA) and Rewet Tests: Refer to the Appendix A of this document for the test method.

The following test criteria apply to the above tests

- a. Brief's performance for the Total Absorbent Capacity, Rewet and ROA tests will be based on the average result of tests performed on each size with five (5) samples
- b. Briefs that utilize reusable one piece tape tab fasteners shall be certified by the manufacturer to be identical in performance to products tested in compliance with the Shuster Test Method TM-299, Tab Refastenability Test for Briefs with a maximum failure rate of 12.5% for a batch of eight (8) random samples tested. This require only applies to adhesive tape type fasteners and not the polymer hook fasteners.
- c. The submittal of test reports including the Total Absorbent Capacity, Rewet, and ROA tests shall be complete and current to within 24 months of testing. Testing shall have been conducted on the current product, model designation and identical construction to the product submitted. All test reports are to be in-hand and furnished upon request.
- d. The product manufacturer shall certify by signature of an officer of the company that data and information submitted is accurate, truthful and consistent with internal test data obtained from the current production of the product submitted for evaluation.
- e. Products which are made by a manufacturer to be distributed under different brand names ("private label" products) may not need to be retested under for each brand name if an officer of the company (the original manufacturer), lists all such products by name and product code, signs and attests that the products are identical in manufacture, construction and performance. Any differences between the original and the rebranded product shall be identified and explained. Acceptance of the original test reports or request for supplemental testing will be determined based upon a review of the products and the information supplied. Authorization shall also be provided by a signature of an officer of the company (the original manufacturer), that the company providing the rebranded product is authorized to use any data acquired on the product by the original manufacturer.
- f. Supplemental independent third party testing may be required for products upon submittal for evaluation if the product or test data submitted is determined different or inconsistent with the

manufacturers published literature, or if inconsistent with results submitted to other states and agencies for the identical products and test methods.

B. Laboratory Requirements

1. Tests are to be performed on the briefs by an independent third party laboratory that routinely markets testing services for the incontinent products industry and as determined by representatives of the Division of Purchase and Contract as acceptable. For the purposes of this document, "an independent third party laboratory" means an analytical laboratory that is not a subsidiary of, affiliated with, or on retainer for, the potential contractor. The following are not considered an "independent third party laboratory" for the purposes of this specification.
 - a. Any laboratory located in a private residence.
 - b. Testing conducted in a manufacturing plant or in a physical laboratory facility owned by, operated by, or otherwise affiliated with the manufacturer of the product being tested.
 - c. Testing performed by employees of, or other personnel hired by, the contracting company.
 - d. The laboratory cannot be owned in whole or in part by the product manufacturer, distributor, provider or any of its parent or subsidiary companies.
2. The independent third party test laboratory shall provide references from a minimum of three incontinent product manufacturers that have had incontinent product testing performed by that test laboratory. Test laboratories submitting references may be requested to submit copies of invoices for previous testing of incontinent products from that independent third party laboratory over the last three years. The State reserves the right to contact companies providing laboratory references for additional details and verification.
3. The laboratory shall provide all documentation requested to verify documented procedures, practices, accuracy and responsible oversight.
4. Test documentation submitted shall include test procedures with the data that is dated and signed by the laboratory technician and a manager responsible for technical oversight.
5. Test reports shall indicate test data in the identical format and units as indicated herein.
6. Future laboratory requirements are intended to require an ISO-17025 quality registration or certification for a testing laboratory from an accredited quality certifier.

C. Other Requirements

1. The brief shall conform to the requirements of Federal Regulation 16CFR Parts 1610 and 1611.
2. The brief may be evaluated for acceptance by a committee composed of representatives of the using hospitals and institutions. The committee, at its discretion, may recommend rejection of any product that it deems not acceptable.
3. The successful contractor shall provide a trained representative who will be available to provide in-service training and follow-up service to the using agency at no cost.

D. Quality Assurance

The State reserves the right to have the bidder submit any product to an independent third party laboratory selected by the state to provide a full test report for a product for which there is a concern that the product construction or performance are not meeting the guarantees and specifications indicated herein during the life of the contract. The sample to be tested may be sourced from the customer's inventory or sourced from a distributor or vendor from current supply. All cost associated with the product purchase, freight and testing shall be borne by the bidder.

Products determined not in compliance with these specifications herein with may be removed from the Qualified Products List for that commodity.

IV. WARRANTY

The contractor warrants to the owner that all products furnished under this specification will be new, of good materials and workmanship, and agrees to replace promptly any product which by reason of defective materials or workmanship shall fail this specification. Such replacement including freight shall be free of any charge to the user or agency.

VI. DELIVERY AND PAYMENT

Delivery and payment for commodities under this specification shall be in accordance with the terms and conditions of the Invitation For Bids. The contractor shall be responsible for any packing, packaging, or protection required to insure delivery in undamaged condition.

VII. ORDERING DATA (For Purchase & Contract Use Only)

Purchasers should exercise any desired option offered herein and should specify the following in the requisition and Invitation For Bids:

1. Title, number, and date of this specification
2. Classification for the performance category and fastener type. (See Section II).
3. Packaging requirements

APPENDIX A

Acquisition Rate and Rewet Test Protocol

SCOPE AND PURPOSE:

1. To measure the ability of an incontinent brief to accept and retain synthetic urine (saline solution) under simulated in-use conditions of load and pressure.
2. To determine amount of time required for an absorbent article to absorb a fixed quantity of a test solution.

DEFINITIONS:

Rewet: Amount of wetness returned to the surface of an incontinent product onto an absorbent filter paper.

Rate of Acquisition (ROA): Number of seconds required to fully absorb test fluid into an incontinent product.

SAFETY AND HANDLING PRECAUTIONS:

Refer to the Material Safety Data Sheet (MSDS) of each reagent for specific information.

REAGENTS:

0.9-% Sodium Chloride (NaCl) Solution

FLUID DOSAGE:

Single dose of 100 ml for small adult size, Single dose of 200 ml for medium, large, and extra-large adult sizes.

EQUIPMENT:

1. 250-ml separatory funnel, discharging 7ml/sec
2. NIST Traceable Timer
3. Stainless steel cylindrical weight 9.8 lbs.: 9.0 cm, 1.0 psi
4. Dosing tube with weight (weight 2.2 lbs, 4" x 4" x 0.5": tube height 9", diameter 1")

5. Filter Paper: AFI Grade 950, 9.0 cm diameter or equivalent filter paper
6. 100-ml volume graduated cylinder
7. Analytical Balance able to weigh to nearest 0.01 grams
8. Product samples

PROCEDURE:

1. Select 5 products for testing and record the production code or date for each sample
2. Precondition the samples at 65 to 70° F for a minimum of 24 hours prior to testing.
3. Prepare the product so it lies flat: Trim the waist elastic and leg gathers, if present; fold under the front and back wing flaps, leaving product target area flat and in contact with test surface area.
4. Measure out a volume of test solution for the product being tested (100ml or 200-ml depending on the product) with a graduated cylinder and transfer the solution to the separatory funnel.

Note: Make sure the timer is ready, as timing for the rewet test will be initiated at moment of delivery of test solution to sample.

5. Center the dosing tube over the target zone. The target zone is at the center of the crotch area.
6. Deliver the test solution into the tube by fully opening the stopcock on the funnel or starting the metering pump.
7. Start the timer when fluid starts to flow from the funnel or pump.
8. Stop the timer when all solution has passed through the topsheet and record the time in seconds as the Rate of Acquisition (ROA).

Note if the fluid leaks around the flat base of the test ring. This is an indication that the absorbent core is not uniform. Highlight this in the test results.

9. Restart the timer and wait twelve (12) minutes.
10. Weigh a stack of dry filter paper and record as weight W1 – the stack should have a dry weight of about 10.0 grams
11. After the 12 minute waiting period, place the stack of preweighed filter paper on the center of the wetted target area.
12. Place a 1.0-psi cylindrical weight on the top of the dry filter paper, making sure the stack is level, not tipping to one side or the other. Start the timer.

Note: The weight should be gently lowered onto the filter paper stack.

13. After one (1) minute, remove the cylindrical weight and the wetted out papers.
14. Reweigh the filter paper stack and record the wet filter paper weight as W2.

Note: If the entire stack of filter paper is wetted, the test is invalid and must be re-evaluated with a new sample using a heavier (5.0-g additional) stack of dry filter paper.

15. Repeat the above steps for all 5 product samples; record each result separately.

CALCULATIONS:

REWET (g) = W2 (Wet filter paper weight) - W1 (Dry filter paper weight)

REFERENCES:

Above test methods were adapted from the following standards.

ERT 150.4-99 Nonwoven Coverstock Liquid Strike-Through Time (Simulated Urine)

ERT 151.2-99 Nonwoven Coverstock Wetback

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