Designation: E787 – 81 (Reapproved 2017)

Standard Specification for Disposable Glass Micro Blood Collection Pipets[1]

This standard is issued under the fixed designation E787; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has been approved for use by agencies of the U.S. Department of Defense.

1. Scope

1.1 This specification covers two dimensionally different disposable glass micropipets used primarily to collect whole human blood specimens for clinical analysis and testing. They are available as coated with heparin or uncoated.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E438 Specification for Glasses in Laboratory Apparatus

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *disposable micropipets*—in accordance with this specification and the expected product performance expressed in this standard, those pipets which are to be used one time only. *Any institution or individual who reuses a disposable pipet must bear full responsibility for its safety and effectiveness.*

4. Classification

4.1 This specification covers two dimensionally different disposable glass pipets as follows:

4.1.1 *Short Pipet*—Approximately 75 mm long and coated with heparin (Type I) or uncoated (Type II). These are commercially recognized as Caraway pipets.[3]

4.1.2 *Long Pipet*—Approximately 150 mm long and coated with heparin (Type I) or uncoated (Type II). These are commercially recognized as Natelson pipets.[4]

5. Materials and Manufacture

5.1 *Glass*—The pipets shall be fabricated from borosilicate glass, Type I, Class B, or soda lime glass, Type II, in accordance with Specification E438.

5.2 *Heparin*—shall be the ammonium salt isolated from the lungs or intestinal mucosa of beef or pork origin. The heparin potency shall be 1 mg of ammonium heparin compound which is equal to at least 100 USP units.[5]

6. Physical Requirements

6.1 *Design*—The disposable glass micro blood collection pipets, both short and long, shall be straight and pulled to a tapered point at one end. Any cross section of the pipets, taken in a plane perpendicular to the longitudinal axis, shall be circular. The pipets shall be lightly firepolished at both ends with no run-in and possess color bands to denote presence or absence of heparin content.

6.2 *Dimensions:*

6.2.1 The short Caraway pipet shall be approximately 75 mm long and 4 mm in outside diameter. The pipet shall hold a liquid volume of 310 to 470 µL. The tapered point length and tip orifice opening shall be as specified in Fig. 1.

6.2.2 The long Natelson pipet shall be approximately 150 mm long and 3 mm in outside diameter. The pipet shall hold a liquid volume of 220 to 420 µL. The tapered point length and tip orifice opening shall be as specified in Fig. 2.

6.3 *Workmanship*—The pipets, as illustrated in Fig. 1 and Fig. 2, shall be free of defects that noticeably detract from their appearance or impair their serviceability. They shall be free of lint, or significant foreign matter, loose or embedded when viewed under normal room lighting. The top and tip ends of the pipets shall be cut at approximately 90° to the pipet axis and shall not be cracked or have jagged ends or chips that enter the bore of the pipet.

6.4 *Color Coding*—Each disposable glass micro blood collection pipet shall be color-coded to identify the pipet. The heparin-coated pipet (Type 1) shall have a red color band. The

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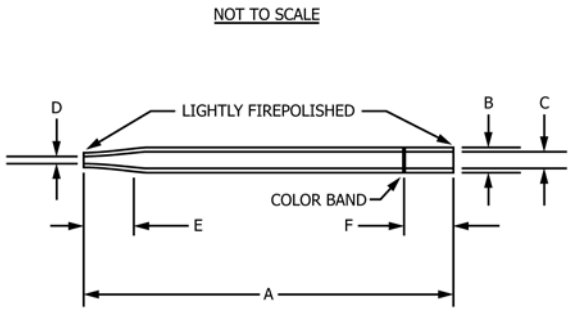
[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Caraway, W. T., and Fanger, H., "Ultramicro Procedures In Clinical Chemistry," *American Journal of Clinical Pathology* , 25, 1955, pp. 316–331.

[4] Natelson, S., Ph.D., *Micro-Techniques of Clinical Chemistry*, Charles C. Thomas, Springfield, Ill., 1961, p. 70.

[5] *The United States Pharmacopeia*, 19th Revision, pp. 229–230.



Capacity: 310 to 470 µL
Coding: Red band-heparin-coated (Type I)
Blue band-uncoated (Type II)

Dimensions in millimetres

A	Overall length	73–77
B	Outside diameter	3.90–4.20
C	Inside diameter	2.40–2.80
D	Inside tip diameter	0.70–1.50
E	Length of taper	6–12
F	Color band location	0–10

FIG. 1 Caraway Pipet

uncoated pipet (Type 2) shall have a blue color band. The location of these color bands shall be as specified in Fig. 1 and Fig. 2.

6.5 *Capillary*—The pipets, both short and long, shall be capable of drawing sheep plasma or human whole blood the full length of the pipet when tested as specified in 7.1.

6.6 *Fluidity* (Type 1, Heparinized, only)—Coagulation of the sheep plasma or human whole blood shall not be evident when viewed under normal room lighting and tested as specified in 7.2.

6.7 *Lot or Control Number*—A lot or control number shall be indicated on the intermediate and outer package of pipets. This lot or control number shall be traceable to the origin (raw material glass and heparin purchases) of the manufacturing record.

6.8 *Resistance to Centrifugal Forces*— The pipets, both short and long, may be subject to centrifugal force under normal analysis or test procedures. No breakage shall result when tested as specified in 7.3.

6.9 *Heparin Coating* (Type 1, Heparinized, only)—The inner surface of the short and long pipets shall be evenly coated with ammonium heparin. A minimum of 5.0 units of heparin activity shall be present in the tube when tested as specified in 6.4. A statement on expected units of heparin and an expiration date may be claimed by the manufacturer. This option may be expressed on the pipet package label.

7. Test Methods

7.1 *Capillarity Test*—Test the pipets, both short and long, for capillarity when held at a near horizontal level. The pipets shall fill with sheep plasma or human whole blood within a maximum of 30 s.

7.1.1 When using a sealant or plastic closure, the pipets should not be filled completely to allow for dry space which will be occupied by the sealant or closure. This step should aid in preventing pipet leakage when handled or centrifuged.

7.2 *Fluidity Test*—Test the pipets, both short and long, for fluidity by using sheep plasma (6.3) or human whole blood (6.4).

7.3 *Sheep Plasma Test:*

7.3.1 *General*—Conduct the test initially by preparing recalcified sheep plasma by the following process:

7.3.1.1 Prepare sheep plasma in accordance with the USP assay for sodium heparin. Add 10 mL of prepared sheep plasma to 2.0 mL of the 1.0 % calcium chloride solution used in the heparin assay. Mix the sheep plasma and calcium chloride solution well.

7.3.2 *Preparation of Controls*—Use samples of both the plain sheep plasma and recalcified sheep plasma as controls in accordance with the following:

7.3.2.1 *Positive Control*—Fill an uncoated (that is, nonheparinized) pipet with recalcified sheep plasma.

7.3.2.2 *Negative Control*—Fill a coated (that is, heparinized) pipet with plain sheep plasma.

7.3.3 *Procedure*—Immediately after the preparation of recalcified sheep plasma, fill the pipets by immersing the tips in the recalcified sheep plasma while holding the pipets near the horizontal level to facilitate quick filling. Rock the pipet several times to assure intimate mixing of plasma with heparin on inner surface of capillary tube. Place the pipets in a horizontal position. At the end of 1 h, inspect the pipets containing plasma for evidence of coagulation by carefully scoring and snapping off segments of tubing and placing them on a flat surface. (Use a black background to facilitate observation and comparison with control sample.) Coagulation has occurred if the sheep plasma becomes opaque or if a fine fibrin thread is noted.

7.4 *Human Whole Blood Test:*

7.4.1 *General*—Human whole blood may be used instead of sheep plasma by following the steps outlined as follows:

7.4.1.1 Fill the pipets with freshly drawn whole blood by immersing the tips in the blood while holding the pipets near the horizontal level to facilitate quick filling.

7.4.1.2 Fill the pipets to within 5 mm from the top (color-coded end) or to approximately 100 mm from the tip on the longer (Natelson) pipet that may be so marked and place in a horizontal position.

7.4.1.3 At the end of 1 h, expell the blood by means of an aspirator and drain on a clean white tissue.

7.4.1.4 Examine the expelled blood with the naked eye under normal room lighting (macroscopically) for the presence of clotting. Coagulation has occurred if a clot of any size is noted.

7.4.2 *Controls*—The testing laboratory shall use a known donor that does not have clotting mechanism deficiencies as a control. Use samples of whole blood as controls in accordance with the following:

7.4.2.1 *Positive Control*—Fill an uncoated (that is, nonheparinized) pipet with human whole blood and run during the test to ensure the suitability of the specimen's clot formation.

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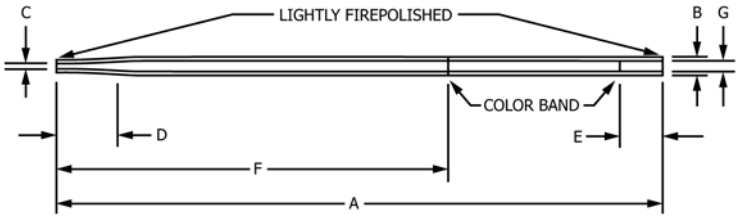

Capacity: 220 to 420 µL
Coding: Red band-heparin-coated (Type I)
Blue band-uncoated (Type II)

Dimensions in millimetres

A	Overall length	145–155
B	Outside diameter	2.80–3.10
C	Inside tip diameter	0.75–1.30
D	Length of taper	6–12
E	Color band location	0–10 top
F	Alternative location	100 ± 1 from tip
G	Inside diameter	1.30–1.80

FIG. 2 Natelson Pipet

7.4.2.2 *Negative Control*—Fill a coated tube (heparinized) from a group of known quality with human whole blood and run during the test to ensure the suitability of the specimen's clot formation from other than lack of heparin (that is, improper technique or specimen handling).

7.5 *Resistance to Centrifugal Force Test*—Fill the pipets, both long and short, with water, sheep plasma, or human whole blood; then seal and suspend in a centrifuge. Accelerate the centrifuge gradually to a speed of 1000 to 1250 RCF. Allow the centrifuge to run at this speed for 10 min only; then shut off and allow to stop without using the brake.

7.6 *Heparin Content Test*—Determine the heparin content in the micro blood collection pipets by the method for assaying sodium heparin specified in the latest edition of the United States Pharmacopeia (USP), or other acceptable methodology that will correlate and provide equivalent test results. The results obtained shall represent the average heparin content on the inner surfaces of the pipets tested. No heparin from the outside of the pipet's surface shall enter the test sample.

8. Keywords

8.1 blood; disposable; glass; heparin; micro; pipet