

BIOHIT FAEX™ Sample System

for the collection and handling of human feces



PRODUCT DATASHEET

BIOHIT FAEX™ Sample System is a sample collection tube intended for the collection, primary containment, preservation, and handling of human feces for further use in diagnostic methods in the laboratory. The BIOHIT FAEX™ Sample System is a multifunctional, CE-marked, IVDR-compliant stool sample collection tube designed for *in vitro* diagnostic use.

OVERVIEW

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| Product name | BIOHIT FAEX™ Sample System |
| Catalog number | REF 602600 (50 tubes/box) REF 602610 (250 tubes/box) |
| Class | IVD Medical Device (Class A) |
| Type | Specimen receptacle |
| Conformity | (EU) 2017/746 (IVDR) ISO 13485:2016 ISO 14971:2019 ISO 6717:2021 |
| Uses | Fecal sample collection, dilution, extraction, centrifugation, dispensing, storage, or use as a component or accessory of test kits. |
| Components | <ol style="list-style-type: none"> 1. Top cap 2. Sample collection stick 3. Collar 4. Tube body 5. Bottom cap |

DESIGN

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|------------------------|-------------------------------------|
| Tube shape | Cylindrical with conical nozzle |
| Collection stick shape | Cylindrical with grooved bottom end |

This is the current specification for this product.

Biohit reserves the right to make changes, in full or in part, at any time without prior notification.

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|------------------|---|
| Base shape | Flat bottom, self-standing on flat surfaces |
| Closure type | Threaded (screw-on) |
| Graduation lines | 1, 2, 3, 4 ml |
| Volume | Min. 1 ml Max. 4 ml |

DIMENSIONS

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|-----------------------------|---------|
| Height | 94.5 mm |
| Max outer diameter (top) | 16 mm |
| Min outer diameter (bottom) | 11 mm |
| Tube body diameter (center) | 12 mm |

MATERIALS & COLORS

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|-------------------------|--------------------------------------|
| Top cap | Polyethylene (PE) |
| Sample collection stick | Polypropylene random copolymer (PPR) |
| Collar | Polyethylene (PE) |
| Tube body | Polypropylene random copolymer (PPR) |
| Bottom cap | Polyethylene (PE) |

PERFORMANCE SPECIFICATIONS

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|------------------------|------------------------------|
| Drop dispensing volume | 37 µl (95% CI, 36.2-37.2 µl) |
| Sample collection mass | 19 mg (95% CI, 18.4-20.0 mg) |
| Centrifugation | Up to 4000 × g, 10 min |

USE & STORAGE

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|--------------------|--|
| Use conditions | -20 to 50°C |
| Storage conditions | 2 to 30°C < 80% RH Away from direct sunlight |