

Tissue Sample Preparation Device for Biochemical Analysis

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Function: The device will grind a frozen tissue sample into a fine powder, replacing the manual mortar and pestle grinding technique currently used. It will also include a cooling method using liquid nitrogen keep the tissue frozen. The sample should be easily collected after grinding.

Client Requirements:

- Sample and tools used must be kept cold at all times during the process
- Must salvage as much of tissue sample as possible
- Processing time should not exceed that for manual preparation (approximately – 15 minutes)
- Device to be used 30 – 40 sample/day
- Grind tissue to the consistency of powdered sugar (10 μ m diameter granules)
- No cross sample contamination

Design requirement:

1. Physical and Operational Characteristics

a. Performance requirements: Tissue should be easily inserted into the device. After grinding completion, tissue sample should be removed and grinding area cleaned before the next sample. Device will be in operation 3 – 5 hours per day. On average the device may have to be turned on 1 -3 times per day. It should be able to grind a soft tissue sample of a maximum sample size of 8 cm³ (2 x 2 x 2 cm). The tissue should remain frozen completely through the grinding experiment.

b. Safety: Liquid nitrogen should be contained to avoid possible contact with skin and clothing. Instrument should be insulated to prevent skin burns. Cryogenic gloves and safety glasses may be required for the use of the device. A means to vent pressure should be included to avoid build up and possible explosion.

c. Accuracy and Reliability: Technique should grind sample to a powdered sugar (10 μ m diameter granules) consistency. The device should provide an optimal means of sample collection.

d. Life in Service: The device should last 5-10 years with proper handling and maintenance. Around 30-40 samples could be analyzed daily.

e. Operating Environment: Device would function in a normal room temperature (approximately 20°C) biochemistry laboratory. An alternative to laboratory bench storage may be storing the entire device or certain components in a -20° C or -80° C freezer. The interior will be exposed to extremely cold (-196° C) temperatures. The exterior may be exposed to freezer condition (-20° or -80° C). The device will be handled by a laboratory technician.

f. Ergonomics: The sample should be easily inserted. The user's hand should not be subjected to a cold temperature during sample insertion. There should be a method for easy refill of the desired coolant (dry ice and alcohol).

g. Size: The device should fit on a laboratory bench with a maximum volume of 0.9x0.61x0.61 m (3x2x2 ft).

h. Materials: Only materials that can withstand cold temperatures can be used (fcc metals such as Nickel, Aluminum, Stainless steel 18-8, Copper). Regular glass and plastics should not be used.

i. Cleaning: Any components of the device that come in contact with the sample should be removable for ease in cleaning and disinfecting (soap and water).

2. Production Characteristics:

a. Quantity: One prototype will be constructed.

b. Target Product Cost: If a pathology lab were to purchase the device, a reasonable range would be \$5000-20,000. For our client's biochemistry laboratory, a reasonable cost for the prototype is \$1,000 – 1,500.

3. Miscellaneous

a. Standards and Specifications: Premarket approval by the FDA will be required.

b. Competition:

i. Polytron system – a homogenizer that operates at room temperature to grind up sample.

ii. Biospec BeadBeater – uses glass or stainless-steel balls to break apart sample, operates at room temperature.

iii. Biospec Cryogenic Pulverizer – uses hammer to crush pre-frozen sample in mortar.

iv. Jet Pulverizer – use air pressure to pulverize sample.