SOP- 'V'/2017 - AQIX® RS-I Biospecimen Sample Procurement

Preamble: The following directives serve to indicate the versatility of the AQIX® RS-I solution in facilitating the procurement of samples of 'normal' or 'malignant' biospecimen tissue under either hypothermic or ambient storage/transport temperatures and the option of dividing the same sample into three segments allowing the operator to simultaneously process 'fresh', formalin fixed (FF) and snap frozen (SF) tissue samples over 1 - 72 hour procurement periods. Likewise, liquid biopsied cell samples (e.g., CTC's) may be processed in a similar manner.

Method 1 – ***Hypothermic*** Storage/Transportation

a) Check that the 8 month shelf-life period on the AQIX® RS-I container label has not expired.
b) Store 125 mL containers of AQIX® RS-I solution @ **3 – 8 °C** in dark conditions.
c) Transport AQIX® RS-I container @ 0-4 °C (over 'wet' ice) to sample retrieval site.
d Maintain AQIX® RS-I container @ 0-4 °C (over 'wet' ice) at sample retrieval site under dark conditions.
e) Open a 125mL AQIX® RS-I container for the minimal time possible before inserting the sample.
f) Quickly attach the lid closure and seal the 125 mL AQIX® RS-I container tightly.
g) Transport back to laboratory @ 0-4 °C (over 'wet' ice) in a polystyrene, outer box.
h) Process as a 'fresh' tissue sample using current proteomic, genomic, metabolomic and/or histochemical technologies, **or**,
i) Further divide the sample into three segments, retain one 'fresh', snap freeze (SF) the second segment and formalin fix (FFPE) the last segment – process each segment accordingly, **or**,
j) Store the AQIX® RS-I container + sample @ **3 – 8 °C** for up to 72 hours under dark conditions prior to proceeding as in h) or i) above.

Method 2 – ***Ambient*** Storage/Transportation

a) Check that the 8 month shelf-life period on the AQIX® RS-I container label has not expired
b) Store 125 mL kit containers of AQIX® RS-I solution @ **15 - 25 °C** under dark conditions.
c) Transport AQIX® RS-I container @ < 25 °C to sample retrieval site.
d) Maintain AQIX® RS-I container @ < 25 °C under dark conditions at sample retrieval site.
e) Open a 125mL AQIX® RS-I container for the minimal time possible before inserting the sample.
f) Quickly attach the lid closure and seal the 125 mL container tightly.
g) Transport back to laboratory @ < 25 °C in a polystyrene, outer box.
h) Process as a 'fresh' tissue sample using current proteomic, genomic, metabolomic and/or histochemical technologies, **or**,
i) Further divide the sample into three segments, retain one 'fresh', snap freeze (SF) the second segment and formalin fix (FFPE) the last segment – process each segment accordingly, **or**,
j) Store the AQIX® RS-I container + sample @ **3 – 8 °C** for up to 72 hours under dark conditions prior to proceeding as in h) or i) above.

Addendum

1. If tissue biopsy contamination becomes a problem then additional AQIX® RS-I solution may be needed to thoroughly rinse the biopsy sample before inserting into the 125 mL AQIX® RS-I container. Additionally, 50-100 mg/L of Chloromycetin or 25-50 mg/L Nanomycopulitin may be added to AQIX® RS-I solution to prevent bacterial contamination without compromising the viability of the biopsy sample.

2. The Table 'V' below indicates the versatility of the AQIX® RS-I solution in allowing the same liquid or solid biopsy sample to be subdivided into three and simultaneously preserved as a 'fresh', frozen (SF) and formalin fixed (FFPE) samples for diagnostic analysis.

Table 'V' - AQIX® Technology – VersatileTissue Biopsy Procurement Methods

Tissue Collection to Prognostics	Current Practices	AQIX® RS-I Protocols
Collection and immediate holding	Biopsy delivered dry/soaked in saline/ wrapped in gauze /formalin fixed/	**Biopsies simply immersed in requisite volume of RS-I @ 3 - 8°C and held or transported before initial pathologist examination**
Transportation	Snap frozen (**SF**), Formalin fixed (**FFPE**) processing or sent as fresh tissues as soon as possible. Long transport times degrade fresh tissues	**Tissues can be maintained 'fresh' in RS-I over ice @ 0 – 4 °C or room temperature (RT) for 12-72 hours before processing – fresh, FFPE and SF samples available.**
Processing	Immediate use of fresh tissues otherwise LIMITED as **SF** or **FFPE** samples	**UNLIMITED choice of techniques – fresh tissues, FFPE and SF are available for analysis**
Analyses	LIMITED by previous **SF** or **FFPE** procedures	**UNLIMITED choice**
Outcomes	Query altered transformation of molecular profiles	**Retains morphological and molecular conformation including functional activity**
Prognostics	***Inconsistent***	***Definitive***