Validation Plan for Lower Volume Blood tubes

Purpose: the purpose of this document is to describe a validation plan for the use of lower volume blood tubes at KHSC. The following tubes are to be implemented:

Product Sample Line Items

Number	Product	Description	Quantity Type	Quantity
1	367841	TUBE K2EDTA PLH 13X75 2.0 PLBL LAV	EA	200 (Total Eaches: 200)
2	368493	TUBE PLN PLH 13X75 2.0 BLCE RD	EA	100 (Total Eaches: 100)
3	367983	Tube SST PLH 13X75mm 3.5ml PLBL Gold	EA	200 (Total Eaches: 200)
4	367960	TUBE PST PLH 13X75 3.0 PLBL L/GN	EA	200 (Total Eaches: 200)

The following departments are within scope in use of these tubes:

Chemistry: the following tubes will be used in Chemistry

1. Product 367841, K2EDTA for tests:
    a. HbA1c
    b. Tacrolimus, sirolimus, cyclosporine
    c. Troponin and BNP
2. Product 367960, PST for tests:
    a. Chemistry analyzer, where indicated within existing workflow
    b. Immunoassay analyzer, where indicated within existing workflow
3. Product 367983, SST for tests:
    a. Chemistry analyzer, where indicated within existing workflow
    b. Immunoassay analyzer, where indicated within existing workflow

Hematology:

1. Product 367841, K2EDTA for tests
    a. CBC

Microbiology:

1. Product 367960, PST for tests:
    a. PCR testing

Transfusion:

1. Product 367841, K2EDTA for test
    a. Type and screen
    b. Antibody identification
    c. Group confirmation

The validation plan is inclusive of the following elements

1. Verification of technical specifications
    a. Tube contents: contents of the tubes to be implemented are proportionally the same as per manufacturer's claims:
    Background:
        i. EDTA
            1. Product 367841, 2.0 mL contains 3.6 mg EDTA
            2. Product 367856, 3.0 mL contains 5.4 mg EDTA
        ii. LiHeparin
            1. Product 367960, 3.0 mL contains 56 Units heparin
            2. Product 367962, 4.5 mL contains 84 Units of heparin

    The functionality of the tube contents will initially be validated using 10 healthy volunteers and collection of blood into each of the low volume tubes. Tube will be processed using automation and quality of the tubes visualized for quality of the sample. Secondly, the use of the low volume blood tubes will be piloted prior to full implementation. The pilot will be done for 1 week in the ICU. The number of sample quality issues will be monitored proactively and audited at the conclusion of the 1 week.

    b. Compatible with automation
    Background:
        i. Vendor affirmation: Abbott has confirmed that each of the low volume blood tubes BD # 367841, 368493, 367983, 367960 are compatible with all aspects of the automation system used at KHSC.
        ii. Low volume tube currently in use: Product ID BD # 367983 is currently in use and has same geometry as all other low volume tubes to be implemented and have thus validated the use of this tube geometry on the automation line. Additionally, as per 3SO, product ID 367841 is currently in use for CBC testing at KHSC.
        iii. Estimation of volume requirements: The volume requirements for all testing performed on Core Chemistry Automation has been verified from 4 different sources. Each of the "C" and "I" analyzers have a dead volume, which is set per each tube use. Using this information, it has been calculated that the low volume tubes will provided adequate volume of serum or plasma for all scenarios of test requests.
        iv. Microbiology sample processing: It has been confirmed that light green tubes may be centrifuged using existing Micro centrifuge configuration

    Compatibility with automation will be validated using 10 healthy volunteers and collection of blood into each of the low volume tubes. Tube will be processed using automation and tested for a comprehensive panel of tests to ensure adequate volume.

Secondly, the use of the low volume blood tubes will be piloted prior to full implementation. The pilot will be done for 1 week in the ICU. The number of sample insufficient sample volume errors will be monitored proactively and audited at the conclusion of the 1 week.

c. Adequacy of tube vacuum:

   There is some concern that the blood tubes may have less vacuum in being claimed "soft draw" which may affect the adequacy of blood volume and acceptance for using by Nursing and Phlebotomy.

   Given this concern, the frequency of insufficient volumes will be monitored during validation. Additionally, the time for complete draw into soft draw tubes will be determined at the time of collected blood from 10 health volunteers. This will be compared to the typical draw time for currently stocked blood tubes.

2. Impact on testing. As mentioned earlier, the technical information for the tubes indicates equivalence in performance of the low volume tube as currently used tubes. With the following exception, it is thus not a requirement to fully validate the use of the smaller volume tubes as the tube type has previously been validated or well established for use and with assay manufacturer's supporting claims.
   a. Validation of 2.0 mL EDTA tube BD# 367841 for use in transfusion medicine. A total of 10 blood tubes will be used to validate for use for type and screen & antibody identification