Procedure: Quality Control Materials and Protocol – VITROS 350

QUALITY CONTROL Materials:

I. Bio-Rad Unassayed Chemistry Controls.

Bio-Rad Controls are to be run:

- Run all levels of control once per shift. (Run daily on day and evening shift.)
- If the system is turned off for more than 2 hours.
- After reloading cartridges that have been removed from the slide supply and stored for later use.
- After calibration.
- After specified service procedures are performed. Refer to the operating instructions for your VITROS Chemistry System.

Preparation

1. Allow frozen control to stand at room temperature (18-25°C) until completely thawed. Thawed materials are stable 14 days at 2-8° C with the following exceptions; DBili and Phos stable 7 days.
2. Swirl gently, do not use mechanical mixer.
3. Date and initial each vial with thaw and expiration dates.

Note:

- Thawed controls are prepared every 7 days and are stored tightly capped at 2-8° C.
- **Do not re-freeze.**
- Store unopened frozen -20°C to -70°C.

Usage

1. Remove bottle from refrigerator and mix well by gentle inversion.
2. Pour off aliquot into a micro cup and cover with evaporation cap.
3. Return control bottle to refrigerator immediately.
4. Allow aliquot to sit at room temperature for only 10 minutes.
5. Analyze immediately.
6. Do not use material past expiration date.
7. Discard if evidence of microbial growth or contamination.

II. Bio-Rad Liquichek® Pediatric Control Level 2.

Bio-Rad Pediatric Level 2 Control is to be run:

- Once per shift. (Run daily on day and evening shift.)
- If the system is turned off for more than 2 hours.
- After reloading cartridges that have been removed from the slide supply and stored for later use.
- After calibration.
- After specified service procedures are performed. Refer to the operating instructions for your VITROS Chemistry System.

Preparation

1. Allow frozen control to stand at room temperature (18-25°C) until completely thawed.
2. Swirl gently, do not use mechanical mixer.
3. Date and initial each vial with thaw and expiration dates.

Note:

- Thawed and opened control is stable 14 days stored tightly capped at 2-8° C. Thaw and expiration date should be noted on vial.
- Thawed and unopened control is stable for 3 months at 2-8°C but should not be used past the expiration date. Thaw and expiration dates should be noted on vial.

- **Do not re-freeze.**
- Store unopened frozen -20°C to -70°C.

Usage

1. Remove bottle from refrigerator and mix well by gentle inversion.
2. Pour off aliquot into a micro cup and cover with evaporation cap.
3. Return control bottle to refrigerator immediately.
4. Allow aliquot to sit at room temperature for only 10 minutes.
   Analyze immediately

II. Ortho Controls "Performance Verifiers" I and II

Ortho Controls "Performance Verifiers" I and II are to be run:

- After calibration, for verification
- While establishing ranges for the unassayed Bio Rad controls (performed once, when new cartridges are put on)
- To troubleshoot an analyte when Bio-Rad control performance is questionable.

Note: The Ortho controls are manufactured specifically for the Vitros dry chemistry instrument.

- **Reconstituted vials stable for 3 days when stored tightly capped at 2-8degrees C.**
  (Alk Phos, Tot Bili, BUBC and Calcium are stable for 3 days. Other analytes stable 1 week.)
- Store unopened frozen -20C or below.
- Store opened refrigerated 2-8 degrees C. **Do not re-freeze.**

Preparation

(Note: keep one set of diluents in the refrigerator to shorten preparation time.)

1. Control and diluent must be at room temperature before reconstitution.
2. Be sure to use the appropriate diluent for each level of control.
3. Gently invert the diluent bottle several times.
4. Gently tap the control bottle to dislodge lyophilized material on the cap to drop down.
5. Add 3.0 ml of the diluent to the control bottle. Discard remaining diluent.
6. Replace stopper and gently invert. Do not shake.
7. It may take up to 30 minutes to dissolve the control material with occasional inversion.
8. Date and initial the vial. Write the 3 day expiration date on the vial
9. Promptly replace stopper and return to refrigerator.

Usage

1. Remove bottle from refrigerator and mix well by gentle inversion.
2. Pour of aliquot into a micro cup and cover with evaporation cap. Return control bottle to refrigerator immediately.
3. Allow aliquot to sit at room temperature for only 10 minutes. Analyze immediately.
4. Values are manually tracked.

QUALITY CONTROL PROTOCOL

1. Run all levels of Unassayed Chemistry and Level 2 Pediatric Bio-Rad control each day of patient testing. (All levels are also to be tested on the evening shift.)

Acceptable:

- All levels of control are within 2 SD for each analyte tested.
- An initial run for each analyte with two levels of controls within 2 SD and one control within 3 SD. For Bilirubin assays, three levels within 2 SD and one within 3SD (If running three levels of unassayed serum QC.)

Unacceptable:

- If one control for an analyte is in 2 S.D. and two are in 3 SD:
    a. Rerun the controls with a fresh aliquot. If still in 3 SD range:
        1. Prepare and rerun new bottles of control. (For Multiqual, prepare a full set.)
    b. If still in 3 S.D. ranges, prepare and run Ortho controls (Performance Verifiers I and II). If the Ortho controls are within range, patient samples can be tested.
    c. Monitor range for the Bio-Rad control(s).
    d. If the Ortho controls are not within range, patient samples can not be tested. Check with key operator to see if slide lot or generation has changed. If not, contact key operator for assistance.
- If all Bio-Rad controls for an analyte are in 3 SD range:
    a. Rerun with a fresh aliquot of controls.
    b. If all still in 3 S.D. range, to expedite testing, run Ortho controls (PV) I and II.
    c. If the Ortho controls (PVs) are in range, patient samples can be tested.
    d. Repeat Bio-Rad with fresh set of controls; evaluate the range on the Bio-Rad controls.
    e. If the Ortho controls (PVs) are not in range, check with key operator to see if slide lot or generation has changed. If not, contact key operator for assistance.
- If all Bio-Rad controls for an analyte are out of 3 S.D. range:
    a. Run the Ortho controls (PVs).
    b. If the Ortho controls (PVs) are in range, patient samples can be tested.
    c. Repeat with fresh set of Bio-Rad controls; re-evaluate the range on the Bio-Rad controls.
    d. If the Ortho controls (Performance Verifiers) are not in range, check to see if slide lot or generation has changed. If not, perform troubleshooting and contact key operator for assistance as needed

2. Record all out-of-range corrective action in the LIS.
3. Record all instrument corrective action in the Vitros QC book.
4. If any out-of-range quality control can not be resolved, notify the supervisor immediately.

KAISER PERMANENTE®

COLORADO REGION PROCEDURE REVIEW

TITLE: VITROS QC	
LABORATORY SITE: **AR and RC**	DEPARTMENT: **LABORATORY**
WRITTEN BY: C. Bersani	WRITTEN DATE: 4/05
REVISED BY: R. Dickey	REVISED DATE: 4/12

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