I. PURPOSE:

The quality control (QC) program consists of both internal and external quality control. The internal QC consists of commercial and in lab prepared materials which are used to verify the accuracy and precision of our test procedures and instruments. Control specimens are tested in the same manner and by the same personnel as patient samples. External Quality control consists of Proficiency Testing material obtained from CAP.

II. INTERNAL QUALITY CONTROL:

A. Beta Thalassemia Short Program by Variant II HPLC D 10 Dual Program

Calibrators and A2/F controls must be run under these conditions:

- Each patient sample run
- Cartridge/reagent change
- PM or service call
- Instrument problems

If calibrators, A2 and F controls are out of range the instruments will stop sampling and the Special Hematology technologist will assess the problem. If it can not be corrected by the technologist, the supervisor will be consulted and Bio Rad contacted for a service call. The problem is written in the problem log. Each instrument has a maintenance log which must be evaluated, signed and dated before the instrument is run for that day. The calibrator and control results are printed and filed after each run. The Variant II and D10 A2 and F control results are entered into the Soft QC program printed and reviewed by the supervisor each month

All FDA approved/cleared tests performed in Special Hematology follow manufacturer instructions without modification. Hb A_2 and F are FDA approved for the Variant II and D10. Abnormal Hb's S, SC, D etc were developed and their performance characteristics determined by our lab. Validation studies are available and the final reports contain a disclaimer.

Variant II
Each Monday a SS & SC patient controls and a carry over test are run on the Variant II instrument. With each cartridge/reagent change a normal and abnormal patient from the previous run is included to verify the accuracy of the new reagents and cartridge.
CAP samples are evaluated by this method twice a year. Linearity completed every 6 months.

D10
Once a week when the D 10 is run, a SS & SC patient control and carry over test is performed and recorded. With each cartridge /reagent change a normal and abnormal patient from the previous run

is included to verify the accuracy of the new reagents and cartridge. Twice a year CAP samples or patient bloods are run on both the Variant II and D10 for our instrument to instrument comparisons. Linearity is completed every 6 months.

B. G6PD

Three commercial controls (Deficient, Intermediate and Normal) controls are run with patient samples. The results are typed into the Soft QC Computer program and reviewed by the supervisor each month. Each control value is checked against the commercial control standards. If the controls are not within the ranges, the patient run is repeated. Cap samples are evaluated by this method.

C. Hemoglobin Electrophoresis

The AFSC commercial control and a known normal patient are run on each cellulose acetate electrophoresis strip and Agar electrophoresis plate. According to our algorithm abnormal results are reviewed by the Residents and Attending who report an impression and diagnosis. Abnormal CAP samples are evaluated by this method and an attending physician.

III. REVIEW OF QUALITY CONTROL:

A. Problems with All controls and instruments should be brought to the Special Hematology supervisor's attention immediately. Instrument problems are written in the problem log of the instrument.

B. Monthly the Special Hematology supervisor will review and print the Levy Jennings report from the Variant II, D10 and G6PD controls and sign off on these QC reports.

C. Whenever a new lot of commercial control is started, the values and ranges are entered into the QC program for G6PD, Variant II and D 10.

D. The control reference sheets are filed in the control binder for each test.

IV. EXTERNAL QUALITY CONTROL:

We perform CAP Hemoglobinopathy (HG) and G6PD proficiency tests.

Proficiency testing samples are performed in exactly the same manner as a patient test. They are integrated into routine patient testing and are performed by the technologist that is assigned to the Special Hematology workstation. Proficiency test specimens and/or results are not shared or referred to other Hematology Laboratories or departments (with the exception of joint lab surveys).

Special Hematology Laboratory Tests with no outside Proficiency Evaluation:

Listed below are those tests being evaluated by blind split samples every 6 months.

- NBT
- Osmotic Fragility
- Pyruvate Kinase Screen
- Special Stains

V. TECHNICAL COMPETENCY EVALUATION OF TECHNICAL STAFF:

For special hematology procedures, each technologist will be directly observed performing a random number of high volume and highly complex procedures annually.

VI. PROCEDURE FOR UNACCEPTABLE SPECIMENS:

Unacceptable specimens (QNS, ID errors, clotted specimens, improper collection, contamination and extended delay to the laboratory) are not tested. Each procedure has listed specific specimen tube types and their conditions for proper testing. For unacceptable specimens proper documentation in the computer is required. This includes reasons for not processing samples as well as a follow-up call to the caregiver (name and title) explaining unsuitability of the specimen. If incorrect data is released, results are immediately amended with a prompt call to caregiver to alert them of changed data.

VII. REAGENTS:

Reagents and solutions are properly labeled, as applicable and appropriate, with the following elements:

- Content, quantity and concentration
- Storage requirements
- Date prepared by the laboratory
- Expiration dates

All reagents are stored as recommended by the manufacturer and as stated in each test procedure. Patient samples are not stored in a frost free freezer.

VIII. GLASSWARE:

Only Class A flasks are used for volumetric measuring. When accuracy and precision are required by Special Hematology procedures do **not** use serological plastic pipettes or graduated cylinders.

IX. VERIFICATION OF MANUALLY ENTERED RESULTS

Manually entered results are immediately reviewed by a verified result report. Verified result reports must not be checked by the resulting technologist. Any technologist can check data entry from a verified result report. The reviewer needs to initial the verified result report.

X. HISTORY:

H-1 Procedure was written by Paula Morris 10/08/99.
H-2 Procedure was revised by Paula Morris 6/12/09.
H-3 Procedure was revised by Paula Morris 12/9/10.
H-4 Procedure was revised by Paula Morris 6/23/11.
H-5 This Procedure was revised by Susan Richardson on 8/8/2012.
H-5 This Procedure was revised by Andrew Link on 11/04/2013