

Control Materials

Dr. Mohamed.A.Mahdi

Laboratory Management and Quality Assurance

(MLS-QUAL-323)

Lecture NO. (19)

Control Materials

- Required for QC program.
- Defined as same sample, to be tested every day when testing is done.
- This type of sample is called control sera.

Criteria for Control Sera

1. Available in sufficiency quantity.
2. Stable-available in convenient vial volumes.
3. Vary minimally in concentration and composition from vial to vial.
4. Closely resemble the specimen in both its physical and chemical characteristics.

5. Safe to use.

6. Not expensive.

7. For hematology analyzer control need to have same consistency and color in human serum.

Types of Control Materials

1. Control sera (pool sera \specimen).
2. Commercially prepared control sera.

Pooled sera

- Is necessary to check errors of bias –
(inaccuracy) in tests.

Preparation of Pooled sera

1. At the end of the day work; collect all the specimens that analyzed in the lab which give normal result to a screw cap container and exclude the following specimen: icteric (Jaundiced)-cloudy (lipemic)- pink color (hemolyzed)- abnormal color (dyes).
(Perform HB antigen test for all specimens).

2. Freeze the pooled sera (collection performed daily and freeze volume up to 1 liter or amount enough for 4 to 6 months).
3. After collection of volume; leave it to dissolve completely at room temperature and transported into large bottle and must be mixed well.

4. Send sample of pooled sera for hepatitis antigen

test. (if +ve; the sera should be discarded and if -ve continue to prepare).

5. Add preservative to the pooled sera as:

1. 100 mg sodium fluoride/dl of serum. Or

2. 1ml sodium borate merthiolate/dl of serum.

6. Mix well; but gently.
7. Centrifuge the pooled sera to precipitate any fibrin or debris for 30 minutes and take the supernatant carefully (if any fats appeared at the surface of supernatant; clear the serum by using cotton or glass wool.

8. Divides the pooled sera into small container (about 1 ml), closed directly, labeled and freeze at -20°C or less.

Commercially prepared control sera

Are available in two forms:-

1. freeze –dried (lyophilized)sera.
2. liquid synthetically manufactured sera.

Freeze-dried control sera

- Preserved at 2-8°C.
- Before the use; read the instructions.
- Open slowly to avoid loss of some substances (you have to use good quality glass ware and special diluents).
- Mix well.

- Leave it at room temperature for 5-10 minutes distributed into small sterile containers (0.5 – 1ml).
- Don not use manual pipettes to avoid contamination.
- Label.
- Freeze.
- Store at -20°C or below until required.

Comparison

	Pooled Sera	Commercially Sera
Advantage	1. v.cheap	1. Safe to use.
Dis advantage	1.Biological hazard (infection)	1.Expensive 2.In some analysis animals sera can not act exactly as human sera.

- This control (pooled +commercially) will detect errors in reagent and STD but not individual pipetting or calculating errors .