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Quality Control of Antisera (Blood grouping sera)

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Abstract:
Quality Control is a terminology covering the procedures used for controlling the quality of many products, from aero planes to electronics goods to food to healthcare. In clinical laboratory, it is the process of all the various methods used to ensure the quality of work and the genuineness of the reports, to detect when problems occur and to help us locate the source of the problem causing wrong diagnosis. The most important person in the clinic or hospital is the patient, and in our concern for the patient we should all want to have a system that will let us know how good our work is, detect any mistakes which are made, including our own, and give us information with which we can improve the accuracy and precision of our work. If our Laboratory testing results are wrong, it may lead the Clinician to make wrong decisions about treatment.[4]
Key Words: Antisera, quality control, reagents, titer, potency, specificity, cells

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Principles for quality control of reagents (Anti sera)

1) Reagents should be of good quality and should have a minimum shelf life of one year.
2) All reagents should be kept at refrigerated temperature of 2-8^{o}C.
3) All reagents should be clearly labeled with lot/batch numbers, date of manufacturing, date of expiry, storage temperature,
4) Manufactures instructions should be strictly followed,
5) Positive and negative controls should be used with each batch in order to ensure the specificity and potency of reagents.
6) Any new reagent introduced should be first thoroughly assessed serologically for its satisfactory quality.[2]

Criteria for quality control

The following parameters are used for the assessment of quality control of reagents.

Appearance

Visual examination of reagents in bright light of any abnormality such as hemolysis, precipitate, particles, haziness any color change

Specificity

1) 1 Clear cut reactions with red cells having the corresponding antigen (s)
2) 2 No reaction with negative controls (O Cells) [3]

Avidity (Reactivity)

It is a measure of the speed with the antiserum agglutinate the red cells.

a) ANTI A

Material Required

- 30-40 % A cells
- Glass Slide
- Anti-A serum
- Applicator stick.
- Pasteur pipette

Procedure

- Put 1 drop of (30-40 %) A cells on a slide
- Add 1 drop Anti-A and start mixing
- Simultaneously start a stop watch
- Stop the watch as soon as agglutination becomes visible

Limit

15 seconds
Appearance should be clear

2. ANTI B

Material Required

- 30-40 % B cells
- Glass Slide
- Anti-B serum
- Applicator stick
- Pasteur pipette

Procedure

- Put 1 drop of (30-40 %) B cells on a slide
- Add 1 drop Anti-B and start mixing
- Simultaneously start a stop watch
- Stop the watch as soon as agglutination becomes visible

Limit

15 seconds
Appearance should be clear

ANTI D

Material Required

- 30-40 % Rh positive cells
- Glass Slide
- Anti-D serum
- Applicator stick
- Pasteur pipette

Procedure

- Put 1 drop of (30-40 %) Rh positive cells on a slide
- Add 1 drop Anti-D and start mixing
- Simultaneously start a stop watch
- Stop the watch as soon as agglutination becomes visible

Limit

60 seconds Appearance should be clear

Anti-Serum	**Test Cells**	**Limit**
Anti-A	Ai A2 A2B	15 Seconds 30 Seconds 45 Seconds
Anti-B	B	15 Seconds
Anti-D	Rh Positive Cells	60 Seconds

Titer (Potency)

It is reciprocal of the highest dilution showed weak agglutination
Denotes the strength of the Reagent [1]

Material Required

- Anti-Sera
- Test Cells
- Test Tube
- Pasteur Pipette
- Centrifuge
- Normal saline

Procedure

1) Label a row of test tubes, according to antisera dilution (1:1 through 1:512)
2) Put 1 drop saline into all tubes except the first tube
3) Add 1 drop antisera to tube 1 and 2 (dilution 1:1)
4) Mix the contents of tube 2 with a clear Pasteur pipette and then transfer 1 drop of the mixture to tube 3
5) Continue the same technique, through all the tubes and remove 1 drop from the dilution tube of 1:512 and discard.
6) Add 1 drop of 5% saline suspension of appropriate red cells to each tube.
7) Incubate for 5-10 minutes.

For Anti-A and Anti-b at room temperature
For Anti-D at 37 degree C

8) Centrifuge at 1000 rpm for 1 minute
9) Gently resuspend the red cells and look for agglutination macroscopically.

Result

The agglutination titer is recorded as the Reciprocal of the highest dilution showing weak agglutination.

Anti-Serum	***Test Cells***	***Limits***
Anti – A Anti – B Anti – D	AB AB Rh (Positive) cells	64, 256 32

Reference:

[1]. Transfusion Medicine Technical manual ED. R.K SARAN,2nd edition.
[2]. Compendium of Transfusion medicine by Dr R.N Makroo.
[3]. Training Module for Blood Bank Medical Officers & Laboratory Technicians.
[4]. C.M.A. I Medical Laboratory Technology by Robert H. Carman.

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