Study of the Stability of various Biochemical Analytes in Pooled Sera preserved at 4-8 °C

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ABSTRACT :

Introduction: Biochemical laboratory plays an important role in today's clinical practice. The reliability of laboratory results is therefore most important. Through the quality control (QC), errors can be minimized and the laboratory can ensure about the reliability of its results. The quality control sera are useful for this purpose. But commercially available quality control sera are costly and not available at all places. Also at peripheral levels the storage of the sera at very low temperature is not possible. So we have studied the stability of various biochemical analytes in the pooled sera stored in readily available refrigerator.

Aims and objectives: To study the stability of various biochemical analytes at 4 - 8 °C in the pooled sera.

Material and methods: We have collected 42.5 ml of pooled sera in a plastic jar and we have added 7.5 ml of ethanediol to it (15%). This pooled serum is tested for HIV and HBS Ag. Then serum is kept in the refrigerator at 4 – 8 °C . Daily 1-2 ml of the serum is taken in a plastic test tube with new micro pipette tip from the jar after thorough mixing. When serum attains the room temperature various tests were performed. The results of the tests were noted. We have compared these results with ERBA multi-calibrated sera.

Observations: We have studied 10 such pooled sera. We have found that total proteins and bilirubin get deteriorated (values varies more than 10%) early i.e. between 18-20 days in all 10 samples. Then alkaline phosphatase and amylase get deteriorated between 22-26 days. Glucose and albumin remain stable for 27-30 days. Cholesterol, triglycerides and uric acid starts deteriorating after 32 days. SGOT, SGPT, LDH deteriorates after 35 days. Urea, creatinine, calcium and phosphorus remain stable for long period i.e. more than 45 days.

Conclusion: we conclude that ethanediol stabilized pooled sera preserved at 4-8 °C can be used for 18 days as internal quality control sera.

INTRODUCTION:

Biochemical laboratory plays an important role in today's clinical practice. Over the year there has been rapid expansion in the field of clinical biochemistry services. As a part of this expansion process, new analytes, new reagents and new instruments have been invented. Biochemical laboratories not only help in early and accurate diagnosis of disease but it also helps in understanding the severity and prognosis of disease. Incorrect laboratory results may lead to the wrong management and possible fatal results. The reliability of laboratory results is therefore most important. There are two types of errors – random errors called poor precision and systemic errors called poor accuracy. Through the quality control (QC), these errors can be minimized and the laboratory can ensure about the reliability of its results. Quality control simply means study of errors and their elimination that will make the laboratory results reliable. Every laboratory personnel should know the importance of quality control and its applications. External and internal quality controls are two different procedures. External quality control helps in comparing our results with other laboratories and to know the systemic errors i.e. poor accuracy. Internal quality

control helps in minimizing the random errors i.e. poor precision. Thus quality control sera are useful for this purpose[1]. But commercially available quality control sera are costly and not available at all places. Also at peripheral levels the storage of the sera at very low temperature (-20 °C) is not possible.

So we have studied the stability of various biochemical analytes in the pooled sera stored in readily available refrigerator (at 4-8 °C).

AIMS AND OBJECTIVES:

To study the stability of various biochemical analytes in the pooled sera at 4 - 8 °C.

MATERIAL AND METHODS:

We have taken a clean wide mouthed plastic jar. Then we have collected sera in various test tubes and allow it to centrifuge for 15 minutes at 2000 rpm. Icteric, lipemic and haemolytic sera are discarded. Then about 42.5 ml of the clear sera is transferred from the test tubes to the plastic jar. This pooled sera is tested for HIV and HBS Ag. Then we have added 7.5ml of the ethanediol (about 15%) to the pooled sera in the plastic jar and mixed thoroughly[2]. This serum is kept in the refrigerator at 4 – 8 °C . Daily 1-2 ml

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of the serum is taken in a plastic test tube with new micro pipette tip from the jar after thorough mixing. Immediately the plastic jar is kept in to the refrigerator and test tube is kept at room temperature. When the serum attains the room temperature following tests were performed on the serum.

A.   Glucose by end point GOD POD method.
B.   Total Protein by end point Biuret method.
C.   Albumin by end point BCG dye method.
D.   Cholesterol by end point CHOD POD method.
E.   Triglyceride by end point GPO POD method.
F.   Bilirubin by end point modified Jendrassic & Groff's method.
G.   Uric acid by end point Uricase-POD method.
H.   Calcium by end point OCPC method.
I.   Phosphorus by Ammonium molybdate , end point method.
J.   Creatinine by Jaffe's kinetic method.
K.   Urea by UV kinetic GLDH method.
L.   SGOT by UV kinetic IFCC method.
M.   SGPT by UV kinetic IFCC method.
N.   ALP UV kinetic PNPP method.
O.   LDH by UV kinetic method.
P.   Amylase by CNPG3, Photometric kinetic method

The results of the tests were noted. We have compared these results with ERBA multi-calibrated sera.

Observations:
We have studied 10 such pooled sera. We have found that total proteins and bilirubin get deteriorated (values varies more than 10%) early i.e. between 18-20 days in all 10 samples. Then alkaline phosphatase and amylase get deteriorated between 22-26 days. Glucose and albumin remain stable for 27-30 days. Cholesterol, triglycerides and uric acid starts deteriorating after 32 days. SGOT, SGPT, LDH deteriorates after 35 days. Urea, creatinine, calcium and phosphorus remain stable for long period i.e. more than 45 days.

DISCUSSION:
Ethanediol is anti-freezing and bacteriostatic agent. Ethanediol stabilized pooled sera does not interfere with any of the above methods of estimation of analytes. WHO document LAB/81.4(7) also recommends the use of ethanediol as a preservative for preparing liquid quality control sera[3].

Some authors studied the stability of the above analytes in ethanediol stabilized pooled sera preserved at -20 °C [4]. But for that deep freezer or Iceland refrigerator (ILR) is required. It is not available at all places. In this case you have to preserve the sera in different small aliquots because there may be chances of conversion of sera into ice at -20 °C.

Preparation of lyophilized quality control sera is also a better option[3]. But its preparation is very expensive and requires expert persons. Also its reconstitution is tedious.

CONCLUSION:
At the end we conclude that ethanediol stabilized pooled sera preserved at 4-8 °C can be used for 18 days as internal quality control sera.

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