

HOW SURE IS REALLY SURE?

the element of doubt

An experienced operator, a proved procedure, carefully made and stored reagents, a reliable reference standard and a good quality colorimeter. This sounds like a formula for consistent accuracy in clinical chemistry. But it still leaves a small margin of doubt.

Even the most experienced operator *can* err, many procedures have small flaws or problems in them, reagents *can* vary from batch to batch or from day to day, reference standards *can* be contaminated and even the best colorimeters are electronic instruments whose parts can wear and whose physical constants can change enough to distort readings.

These probabilities of error—however small they may be individually—add up to an area of uncertainty. In positive terms they present a challenge to the clinical chemist, an opportunity to increase still further the assurance of reliability.

a theoretical solution

In outline, the problem is simple. Whether reference standards are used or not, most steps of the tests are uncontrolled: if they are wrongly performed or are subject to chemical or mechanical error this is not revealed by the procedure itself.

The theoretical solution is, therefore, to add to the performance of the test a control which checks on the accuracy and validity of each and every step taken to produce the result.

our contribution

In pursuit of the theoretical solution mentioned above we devised two substances 'Lab-trol' and 'Patho-trol.'

Their composition is known and is very finely controlled to be similar to whole blood or serum. Each of them contains known concentrations of sixteen substances.

As their name suggests, they are used as controls in testing for the sixteen substances they contain. A specimen of 'Lab-trol' or 'Patho-trol' is run through with each batch of tests. When the results are read the concentration reported for the control should agree with the known content. If it does not agree a complete check should be made on the whole of the test procedure.

'Lab-trol' contains concentrations within the normal range. 'Patho-trol' contains concentrations within the pathological range.

how sure are we?

Obviously, the value of these control sera depends upon the precision with which their contents are known and upon their stability. The control sera are prepared from normal serum and are presented in a clear, stable liquid form. In order to ensure good stability it is necessary to completely remove the glycolytic agents, lipids and other water insoluble material, by a series of fractionation steps. The concentration of the constituents is readjusted to the desired values and the sera are then sterilized by filtration.

Perhaps the clearest proof of our success in maintaining stability is embodied in the following table which compares the values in a very early batch of 'Lab-trol' with a check test made on the same material almost seven years later. As can be seen, the values vary hardly at all.

'Lab-trol' Lot No. 11A

Prepared January 7th, 1954
Stored at refrigeration temperatures
2° to 10°C, (35° to 50°F.)
Re-checked December 22nd, 1960.

| | Values established Jan. 7th, 1954 | Values found on re-checking Dec. 22nd, 1960 |
|------------------------|--|---|
| | per 100 ml. per 100 ml. | |
| Total Protein | 6.6 gms. | 6.6 gms. |
| Glucose | 112 mg. | 112 mg. |
| Non-protein nitrogen | 30.7 mg. | 31.6 mg. |
| Blood urea nitrogen | 10 mg. | 10.1 mg. |
| Creatinine | 1.3 mg. | 1.2 mg. |
| Chlorides (as Na Cl) | 545 mg. | 545 mg. |
| Phosphorus (Inorganic) | 2.56 mg. | 2.56 mg. |
| Calcium (Total) | 10.1 mg. | 10.1 mg. |
| Sodium | 333 mg. | 333 mg. |
| Potassium | 20 mg. | 20 mg. |
| Magnesium | 2.48 mg. | 2.48 mg. |

summary

Two products—'Lab-trol' and 'Patho-trol' can add considerably to certainty in clinical chemistry. Used as controls they can establish a system of quality control on laboratory work in a wide variety of blood and serum tests by revealing faults in technique, materials or equipment at every stage of the test procedure.

also available

'Enza-trol', an enzyme control. 'Iodo-trol' standardized control for protein-bound iodine procedures. 'Cholestrol' a stable liquid control for cholesterol procedures.

would you like to know more?

The foregoing is merely the briefest possible summary of both the rationale for the use of controls and the many interesting aspects of these products. If you would like to know more about the subject we will gladly send you a copy of our booklet 'Accuracy in Clinical Chemistry' which covers the whole case and suggests a procedure for quality control which many people have found to be of use and value. Why not send for a copy straight away?

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