

Homogeneity bacteriology

1. IPH (Belgium)

Control at IPH (3 samples): identification, count, purity,

Control by (9) expert labs: identification, purity: acceptance of samples (NB min. nb. exp.labs = 5)

Homogeneity = based on results expert labs (80%)

2. CMPT (Canada)

Random sample of production lot is tested either by 15% sample with requirement of 95% homogeneity with group and reference value or application of Mil-Std 105E with 99% acceptance.

See: N.A. Farnum. Modern Statistical Quality Control and Improvement. Duxbury Press 1994.

3. FVSOK (Russia)

Ziehl-Neelsen AFB microscopy: total number of participants – 1500, two surveys per year, control slides set: 6 unstained (6 different lots with different load of AFB) and 2 stained slides from the same lot of slides as two of the unstained. AFB content and lot homogeneity is established by microscopy of 15% of randomly sampled slides by three different specialists (reading of 3 different regions of 100 fields of each slide tested) in similar conditions. Slides' variation is estimated for each lot. Homogeneity of smears is evaluated by comparison of microscopy results of AFB content in each of the three regions of the slides tested.

Fluorescence AFB microscopy: total number of participants – 150. Two surveys per year, control slides set: 8 unstained slides (8 different lots with different load of AFB). Attestation and homogeneity testing – as for Ziehl-Neelsen AFB microscopy, 10% of slides tested.

M. tuberculosis culturing: total number of participants – up to 200, one survey per year, a set of 10 cryovials with bacterial suspensions of different bacteria (included mixes of M tuberculosis and non-mycobacteria and M. tuberculosis in different concentrations). Homogeneity of samples in a lot (content of bacteria specific to a particular lot) results from the way of their preparation: each lot is prepared from one pool of a bacterial suspension prepared from a well-characterized strain from the Federal collection). Lots' homogeneity is evaluated by the laboratory-manufacturer and is confirmed by 5 expert laboratories.

M. tuberculosis culturing and DST in liquid media: total number of participants – 36, other - as in M. tuberculosis culturing module.

M. tuberculosis Drug Susceptibility Testing: total number of participants – up to 180, one surveys per year, a set of 20 Lewenstein-Jensen slants with M. tuberculosis bacteria with different Drug susceptibility characteristics (8 drugs). Homogeneity of samples in a lot (uniformity of DST characteristics of samples of each lot) results from the way of their preparation: each lot is prepared from one pool of a bacterial suspension prepared from a well-characterized strain). Lots' homogeneity is evaluated by the laboratory-manufacturer and is confirmed by 10 expert laboratories.

Clinical microbiology: total number of participants – up to 900, two surveys per year, a set of three vials with lyophilized bacterial suspensions of different strains or mix of

suspensions of different strains. Homogeneity of samples in a lot (content of bacteria specific to a particular lot) results from the way of their preparation: each lot is prepared from one pool of a bacterial suspension prepared from well-characterized strains from the Federal collection). Lots' homogeneity is evaluated by the laboratory-manufacturer and are confirmed by 10 expert laboratories.

4. CSCQ (Switzerland)

We do not produce our samples. We demand to all our providers a lot-specific certificate of homogeneity for every sample we order.

5. INSA (Portugal)

The Mycobacteriology microscopy smears are analysed by the team of mycobacteriology laboratory before they are send to the participants. In case of disagreement the participants send the samples to be reevaluated.

The rubeola, toxoplasmosis, brucella, syphilis, hidatidose samples and the faecal samples are also analysed before they are send to the participants.

The other programs are sent by Labquality.

6. UK Neqas (England)

1. Pre and post distribution testing in house - 10% sample of bulk material.

2 Additional samples sent for confirmatory testing in relevant expert reference laboratories for pre- and post distribution.

3. Review of participants' results and analysis of concordance with the intended result.

7. QualiCont (Hungary)

Before the surveys the expert of the bacteriology scheme evaluate the samples with examines minimum 2 sets of them with the same way as the other participants of the schemes.