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Sample production microbiology IPH

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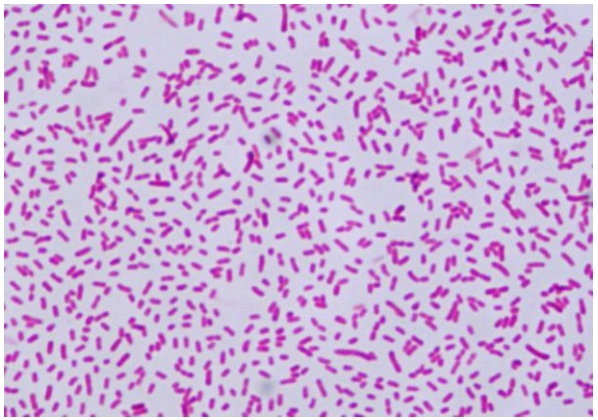
BACTERIOLOGY

Samples

Strains

- “Expert” laboratories
- Other laboratories
- Other QC providers



Each strain is controlled on purity and identified after reception

Can be evaluated by experts before production

Production of samples

Culture

Lyophilization or production of simulated samples (stool, urine, swabs, skin scrapings)

Internal control of samples

External control of samples (experts)

Internal control of lyophilized samples

6 samples from different stages of the distribution:

- 2 at the beginning
- 2 in the middle
- 2 at the end

Growth control

Purity

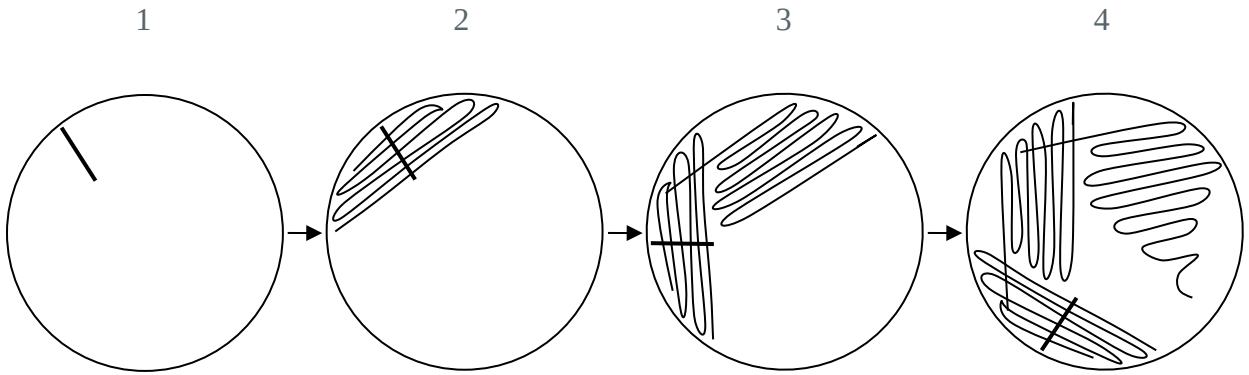
Identification

Growth control

After each lyophilization

If > 3 mths between production – send out: repeated

Semi-quantitative (calibrated loop 10 µl)



Growth control: interpretation

Interpretation (based on own experiences):

- Rare: 1-9 col/part1 = 100-900 col/bottle
- Few: 10-90 col/part1 = 1000-9000 col/bottle
- +: ≥ 100 col/part1 = ≥ 10 000 col/bottle
- ++: growth part 2 = ≥ 50 000 col/bottle
- +++: growth part 3 = ≥ 100 000 col/bottle

Validation:

- At least ≥ 10 000 is necessary

Purity

No contamination is allowed

Identification

Must be in concordance with presumed identification

Internal control of simulated samples

All material used in production of the samples is controlled on sterility

Samples are controlled on:

- Growth
- Purity
- Identification

Samples are chosen at random from beginning, middle and end of the production

Performance of control

Control is performed:

- Immediately after production
- Weekly during storage of the samples (growth, (purity)); can be daily in case of “difficult” organisms
- Prior to sending and 1-2 weeks after sending (repeat samples)

Growth control

Pathogens

Commensals

Relation between both (depends on sample, may differ from one survey to the next)

Evaluated during conservation

External control

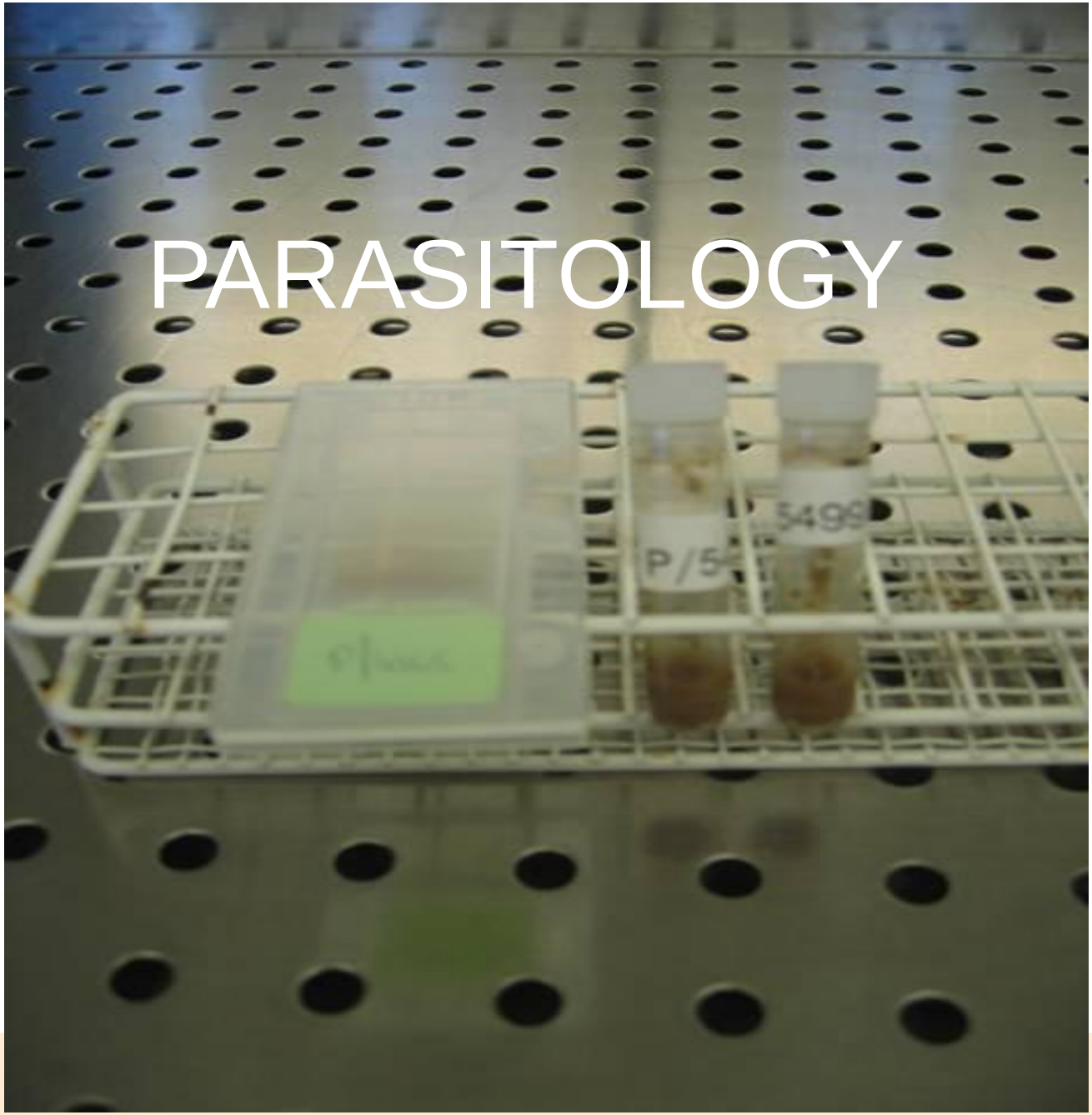
Samples are evaluated by a committee of experts (n = 8 (min. needed 5))

Samples are treated as routine samples; evaluation of growth, purity, identification, antibiogram

Conclusion about utility and usefulness of samples

At least 80% of the results must be in concordance

PARASITOLOGY



Internal control: stool samples

Preparation: stool + formol (volumes depend on available volume of stool, nature and concentration of parasites)

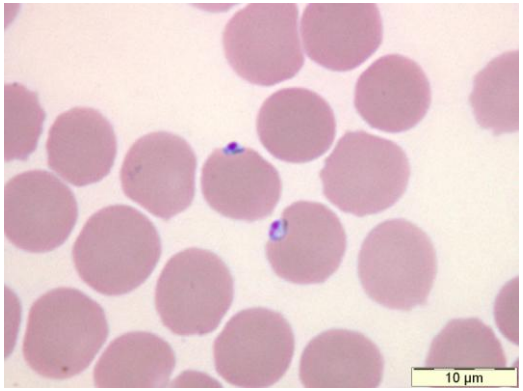
Homogenization by mixing (20')

Distribution in samples 1 ml

Control of 10 random samples: visual microscopic evaluation: each sample must contain sufficient number of parasites

Internal control: blood smear

Malaria: microscopic examination of 10 (stained) samples is sufficient



Other (e.g. microfilaria): every smear is examined on presence of parasites (unstained); “negative” smears are discarded

External control

Samples are evaluated by a committee of experts
(n = 10 (min. needed 3))

Samples are microscopically examined

Conclusion about utility and usefulness of samples

At least 66% of the results must be in concordance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