



BIO-DEV s.r.l.
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**Internal audit from BIO-DEV s.r.l., Via A. Ressi 26, 20125
Milano, Italy**

BIO-DEVELOPMENT is an independent company, founded in 1990, organizing external quality assessment schemes for diagnostic manufacturers, scientific associations and Italian regions in accordance with the Italian legislation (decree from 10/2/1984 to be implemented by regional authorities).

An internal audit was performed in the office of BIO-DEV on April 10 and 11 1995.

We appreciated the open discussions we had with all the staff members and could have a direct access on all our questions.

Based on our investigations we can conclude the following:

1. As BIO-DEV is independent from diagnostica manufacturers and distributors, the EQA schemes run by this company offer guarantees for objective evaluation of participants.
2. The confidentiality of the participants is assured by a coding system, only known by BIO-DEV staff members.
3. BIO-DEV has adequate computer and software facilities to evaluate EQA results and to produce the reports.

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4. BIO-DEV has a written documentation for:
- the organisational structure of the company
 - description of tasks and duties for every staff member
 - standard operation procedures for:
 - sample requirements
 - sample mailing
 - coding of participants
 - the time schedule of each scheme
 - the statistical evaluation
 - treatment of external complaints
 - macro's for the statistical evaluation
 - detailed description of each scheme: (subscription, instructions, reply forms, data management, time schedule,..)

In our interviews with the staff members, we could assess that they exactly known the instructions and perform their tasks as described.

5. We could examine several reports in different fields from clinical laboratory medicine.

These reports are well presented and easy to understand by the participants. Data are often illustrated by graphs and Youden plots.

The long-term performance follow up presented as a follow-up of z-scores is very useful for the participants.