2Form No. 9

Specific Information for On-site Assessment for Surveillance

Part I: General information

1. Accreditation in compliance with standard: ☐ ISO/IEC 17025 ☐ ISO 15189 ☐ ISO 15190 ☐ ISO 22870 ☐ ISO 17034 (RMP type No. …. (1 to 8 according to R 07 15 004) ☐ Other……..

2. Is there a combination of on-site assessment?

☐ No (Only surveillance) ☐ Yes (Objective for surveillance with ○ Reassessment ○ Extended scope ○ Other…….)

☞ **3.** Name of laboratory .....

Address of laboratory .....

.....

4. Nomination a senior staff member as a representative in all dealings with BLQS, DMSc.

Name…….Position……..

Telephone……..... Fax …….....

Mobile……..... E-mail.....

5. Name of key person

Name of Top management/Laboratory management…… Position…….....

Name of Quality manager…….....…Position.……...

Telephone……..... Fax …….....

Mobile……..... E-mail.....

Name of Technical manager…….....Position.…….

Telephone……..... Fax …….....

Mobile……..... E-mail.....

Name of Laboratory safety officer ……..

In case of laboratory has other standard such as ISO 9001, ISO 14000, ISO 14001, ISO 22000.

Please specify name of top management ……..

Position……

☞ **Part II : Specific information : Test item submitted for accreditation. (Please clearly identified if there is any changed from last accreditation)**

(1) No.	(2) Status	(3) Type of Sample	(4) Test	(5) Method / Standard of procedure's laboratory	(6) Principle/ Technique/ Equipment	(7) Purpose of the test	(8) Work load (No. of samples / year)	(9) Proficiency Testing, PT	(10) Interlaboratory Comparisons	(11) Intralaboratory Comparisons
								Matrix : …… **Test** : …… **Name of PT provider** :…… **Date participated** : …….. **Result** : …….	**Matrix** : …… **Test** : …… **Name of laboratory compare** : …….. **Date** : …… **Result** : ……	**Matrix** : …….. **Test** : …… **Number of member** :…….. **Date** :…… **Result** : ……

*** Note : additional sheet of paper**

- **No.8 If laboratory have not sample from sample receipt to test report that the sample is not quality control such as sample of PT, Bureau of Laboratory Quality Standards shall not accept of application.**
- **Applicant laboratory is required to submit information on their participation and performance in PT activities or its plan to participate in PT activities relevant to the scope applied, where available.**
  - **No.9 -11 Laboratory shall submit of summary report of PT, interlaboratory comparisons or intralaboratory comparisons of each test with satisfied result of report of activities to determine the real root cause and remedial corrective action of unsatisfied result.**
  - **No.10 If participate of interlaboratory have more than three laboratories, you will identify name of laboratory compare and number of participate.**

    If participate of interlaboratory have not more than three laboratories, you will identify all name of laboratory compare.

6. Quality management system

6.1 The date of current internal audit.

.....

6.2 The date of current management review.

.....

6.3 Complaints. Total…….. please specify:.....…….

.....

7. Personnel

7.1 Supervisor and analyst names

(who engaged in every step of the method) and work history.

Name	Position	Responsibility	Qualification	Experience/Year

7.2 Signature of person proposed for approved signatory in each requested accreditation tests and the documents demonstrated the qualification and competence in those accreditation test.

Name	Position	Qualification	Accredited test that assigned for approved signatory	Signature of approved signatory

☞ **8. Reference material, reference standard and equipment that affect the accuracy of test results** (shall calibrate)

(Please record in ordering: reference material , reference standard, major equipment and minor equipment that shall calibrate)

Reference material, Reference standard/ Equipment	Lot/Model	Responsible person	Calibration frequency	Date of last calibration	Name of calibration service

☞ **9. Attach herewith quality documents apply for accreditation** (Quality manual or other names, SOP, QP or other names, WI, WS, F etc. according to the related international standard for accreditation) and master list of quality documents. Please specify the title, code, revision No., issued date, approved date, effective date.

……

……

☞ **10. Attach here with the reference of test methods requested for accreditation** (please attach each reference methods for each accredited tests)

……

……

11. Medical laboratory sample collection site (Include inside, outside branch and mobile unit)

No.	Name of sample collection site	Place	Remarks

12. Attachment (Those attachments are attached with item 1. – 12. and including with these followings:)

- ❑ 1) Quality manual
- ❑ 2) Procedures
- ❑ 3) Work instructions
- ❑ 4) Worksheets / Forms
- ❑ 5) Customer manual
- ❑ 6) Master list of quality documents
- ❑ 7) Technical standards / references of each test item
- ❑ 8) Internal audit report
- ❑ 9) Management review report
- ❑ 10) Method validation report
- ❑ 11) Method verification report
- ❑ 12) Homogeneity study report (for accredited RMP)
- ❑ 13) Stability study report (for accredited RMP)
- ❑ 14) Characterization of property values report (for accredited RMP)
- ❑ 15) Measurement uncertainty report
- ❑ 16) The set of hard copy and electronic media in CD/DVD (contained with all of documents were submitted which are in the general kind of file and easily read by the general program and version. Any filled from BLQS-DMSc is in MS-word file.
- ❑ 17) .....
- ❑ 18) .....
- ❑ 19) .....

Signature ……

Authorized person name (……..…….)

Date (date/month/year) …….