CLINICAL PERFORMANCE STUDY PROTOCOL

A.1 General

The purpose of the document is to ensure the clinical performance study is performed to yield high quality, accurate and reliable data for the IVD medical device under investigation.

A.2 Identification and description of the IVD medical device under investigation

a) Summary description of the IVD medical device under investigation and its intended use.
b) Name of the IVD medical device, including software and accessories, if any, intended use including populations and indications of the IVD medical device under investigation in the proposed clinical performance study.

A.3 Identification of the clinical performance study protocol

a) Title of the clinical performance study.
b) Reference number identifying the specific clinical performance study, if any.

A.4 Sponsor

Name and address of the sponsor of the clinical performance study, when testing is occurring externally to the sponsor's site.

A.5 Principal investigator and study site(s)

a) Name, address, and professional position of principal investigator(s).
b) Name and address of the study site(s) in which the clinical performance study will be conducted.

A.6 Overall synopsis of the clinical performance study

A summary or overview of the clinical performance study shall include all the relevant information regarding the clinical performance study design, such as inclusion/exclusion criteria, number of specimens and, when applicable, subjects, duration of the clinical performance study, objective(s), endpoint(s).

A.7 Risks and benefits of the IVD medical device under investigation and clinical performance study

a) Anticipated adverse device effects.
b) Anticipated adverse events associated with the study other than those associated with the IVD medical device, e.g. during specimen collection
c) Residual risks associated with the study, as identified in the risk analysis report.
d) Steps that will be taken to control or mitigate the risks.
e) Risk-to-benefit rationale.

A.8 Design of the clinical performance study

A.8.1 General

Justification for the need for an interventional study design or the need for specimens primarily collected for the study which pose additional risks for the subject.
Rationale for the choice of the type and design of clinical performance study to be performed in relation to the intended use of the IVD medical device under investigation.
Description of the measures to be taken to avoid bias (considerations of bias from, for instance, population, test protocol, reference measurement procedure, interpretation and analysis), including when applicable randomization and blinding/masking.

A.8.2 IVD medical device under investigation and comparator(s)

Justification of the choice of comparator(s).

A.8.3 Specimens and when applicable, subjects providing specimens

a) Method of specimen collection
b) Inclusion / Exclusion criteria for subjects providing specimens.
c) Criteria and procedures for subject withdrawal or discontinuation.
d) Total expected duration of the clinical performance study.
e) Volume of specimens to be collected, and number of subjects providing specimens required to be included in the clinical performance study.
f) Specimen storage, handling, processing, transport, and disposal.

A.8.4 Procedures

Description of all clinical performance study related procedures subjects will undergo during the clinical performance study.

A.8.5 Monitoring plan

Detailed plan to be followed for monitoring the clinical performance study, including access to source data and the extent to which source data will be verified.

A.8.6 Data management

Detailed plan to be followed for data management for the clinical performance study, including access to source data and the extent to which source data will be verified.
When electronic databases or remote electronic data systems are used, written procedures shall be implemented to establish, verify and validate for the electronic data system.

A.8.7 Statistical considerations

The description of and justification for:

a) expected drop-out rates, when applicable;
b) criteria for the termination of the clinical performance study on statistical grounds, when applicable;
c) the specification of subgroups for analysis;
d) the treatment of data, including drop-outs and withdrawals.

A.8.8 Deviations from clinical performance study protocol

The description of and justification for:

a) procedures for reporting any deviation(s) from the original statistical plan;
b) emergency contact details for reporting serious adverse events and serious adverse device effects;
c) notification requirements and time frames.

A.8.9 Accountability of IVD medical devices under investigation

Description of the procedures for the accountability of IVD medical devices under investigation, including procedures to ensure that access to IVD medical devices under investigation shall be controlled and these devices shall be used only in the clinical performance study and according to this document.

A.8.10 Adverse events, adverse device effects and device deficiencies

Description of how to categorise, evaluate and report adverse events and device deficiencies which could result in a serious adverse event. Description of how to categorise, evaluate and report adverse events and device deficiencies which could result in a serious adverse event. Where the study uses specimen collection procedures that pose no additional risk to the subject, in exceptional cases, there might be adverse events impacting the subjects.

A.8.11 Vulnerable population (if applicable)

a) Description of the vulnerable population.
b) Rationale for including vulnerable population
c) Description of the EC's specific responsibility.
d) Description of what medical care, if any, will be provided for subjects after the clinical investigation has been completed.

A.8.12 Suspension or premature termination of the clinical investigation

a) Criteria and arrangements for suspension or premature termination of the entire clinical performance study or of the clinical performance study at one or more study sites.
b) Criteria for access to and breaking the blinding/masking code in the case of suspension or premature termination of the clinical performance study, when the clinical performance study involves a blinding/masking technique.
c) Requirements for subject follow-up and continued care.

A.8.13 Publication and Communication policy

Statement indicating the conditions under which the results of the clinical performance study will be offered for publication.

A.8.14 Bibliography

List of bibliographic references pertaining to the clinical performance study, when applicable.