

(For Your Reference)

Please attach the following papers to the application in accordance with the insurance division of D-1 or D-2:

(Case of insurance division D-1)

- 1) Number of tests per kit
- 2) Cost of kit (cost per test)
- 3) Requested score and basis
- 4) Market predictions (predictions of number of patients and tests)
- 5) Summary of study (theory, determination method, comparison with other methods, efficiency etc)
- 6) References showing clinical efficacy
- 7) Other reference materials

(Case of Insurance Division D-1)

- 1) Number of tests per kit
- 2) Cost of kit (cost per test)
- 3) Requested score and foundation
- 4) Market predictions (predictions of number of patients and tests)
- 5) Summary of study (theory, determination method, comparison with other methods, properties, etc)
- 6) Clinical efficacy compared with conventional methods
- 7) Other reference materials