3-3. Applications

Division D-1

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

Division D-2

1. Number of tests per reagent
2. Cost of reagent (cost per test)
3. Requested score and basis
4. Summary of study (theory, determination method, comparison with other methods, properties, etc.)
5. Clinical usefulness compared with conventional methods
6. Other reference materials

4. Determination of Treatment in Terms of Insurance and Notification of Determination

When an application for insurance is submitted, treatment of fees for examination and treatment is determined using the following divisions after investigating the details of examination and treatment:

1. In-vitro diagnostic drugs for new determination items (division D-1)
   Insurance used within 6 months after approval.
2. In-vitro diagnostic drugs for new determination method, but not new determination items (division D-2)
   Insurance introduced periodically 4 times a year.

When treatment of fees for examination and treatment is determined, applicants of use of insurance are quickly informed of the results of these determinations.

5. Inquiries into Opinions of Manufacturers and Importers

When determining how to handle fees for examination and treatment, opinions of manufacturers and importers pertaining to this application are obtained before determinations. It is important to take the time to listen to these opinions.

Once the aforementioned procedures have been completed, insurance can be applied and basic market activity of each company is developed. Consequently, it takes a period of approximately 1 year from the time of application for approval of manufacture or import.