Sample Record Form

Client Name: .....

Company / Affiliation / Institution .....

Address .....

Tel: .....Fax: .....E-mail: .....

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1. Desired Testing for Medical Devices (☑ Check the empty box)

**Regular Track* means that the client will receive the service within 60 days from payment date.

***Fast Track* means that the client will receive the service within 14 days from payment date.

Test	Normal*	Fast Track*	Code (For Staff Only)
1. Cytotoxicity Testing			
1.1 ISO certified (in-scope)	☐ 20,000 Baht	☐ 30,000 Baht	
1.2 ISO uncertified (out-of-scope)	☐ 15,000 Baht	☐ 24,500 Baht	
2. Hemolysis Testing	☐ 28,000 Baht	☐ 49,500 Baht	
3. Skin Irritation Testing	☐ 40,000 Baht	☐ 80,000 Baht	
4. Composition Analysis	☐ 3,700 Baht	☐ 7,000 Baht	
5. Microbiology Testing			
5.1 Bioburden Testing	☐ 6,600 Baht	☐ 20,100 Baht	
5.2 Bioburden Validation (Staff Only)	☐ 3,700 Baht	☐ 9,000 Baht	
(sample without pores/threads/fiber)			
5.3 Bioburden Validation (Staff Only)	☐ 7,000 Baht	☐ 15,000 Baht	
(sample with pores/threads/fiber)			
5.4 Sterility Testing (*14 days testing period*)	☐ 6,8000 Baht	☐ 19,500 Baht	
5.5 Antibacterial Susceptibility testing			
☐ Agar Diffusion Method ☐ Broth Dilution Method			
5.5.1 *Staphylococcus aureus*	☐ 2,000 Baht	☐ 5,600 Baht	
5.5.2 *Staphylococcus epidermidis*	☐ 2,000 Baht	☐ 5,600 Baht	
5.5.3 *Pseudomonas aeruginosa*	☐ 2,000 Baht	☐ 5,600 Baht	
5.5.4 *Escherichia coli*	☐ 2,000 Baht	☐ 5,600 Baht	
5.5.5 *Staphylococcus aureus MRSA* (drug resistant)	☐ 2,000 Baht	☐ 5,600 Baht	
5.5.6 Candida albicans	☐ 4,000 Baht	☐ 12,000 Baht	
5.5.7 *Porphyromonass gingivalis*	☐ 9,500 Baht	☐ 28,000 Baht	

Note : *For test item No. 3 (Skin Irritation Testing), the Regular Track : the client will receive the service within **120 days** from payment date. For the Fast Track : the client will receive the service within **9 weeks** from payment date.*

2. Issuing Test Results (Customer will receive one Thai version of the Test Report as default)

Requesting additional Test Results
◯ English Version of the Test Report **(4,200 Baht)**
◯ Thai Version of the Supporting Document **(4,200 Baht)**
◯ English Version of the Supporting Document **(4,200 Baht)**

Note *: The Supporting Document includes details about sample preparation, testing process, and qualitative test result*

3. Details of Sample (for test report)

3.1 Name: .....

3.2 Product Description : ◯ Solution ◯ Powder/Pellets/Drug ◯ Film/Sheet/Tube
◯ Solid (Select : Rubber / Polymer / Foam
◯ Fiber / Porous / Textiles ◯ Others (specify).....

3.3 Product Properties : ◯ Absorption value.....(ml./sample)
◯ Soluble (Select : Filterable / Not Filterable) ◯ Insoluble

3.4 Model ..... Grade .....Color ..... Size / Volume .....cm / ml
Lot Number .....Amount .....gram / sheet / roll / set
Manufacturer ..... Country .....Dealer .....
Additional Notes: .....

3.5 Storage condition: .....

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4. Supporting Documents for Samples ◯ No ◯ Yes ◯ Others (specify) .....
Warnings / Cautions / How-to-use ◯ No ◯ Yes ◯ Others (specify).....

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5. Company's Name and Address specified in the Test Report

Name - Address .....
.....

6. Company's Name and Address specified in the Tax Invoice

☐ According to the Test Report
☐ Others (please specify).....
.....
Tax Identification Number.....Branch.....

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7. Payment

◯ Cash ◯ Transfer

8. Receiving Test Report ◯ In person ◯ By post office, to the address indicated above ***

Or another address specified here: ……
……

9 Receiving Samples ◯ In person, along with the Test Report
◯ By mail, along with the Test Report *** ◯ By mail, according to the address in (No. 5.) ***

***Additional shipping cost will be applied

Note : *The laboratory will send the test report by mail within 3 business days from the date stamped on the document.*

10 **Decision Criteria** (Referenced according to ILAC G8:09:2019 Guidelines on Decision Rules and Statement of Conformity)

In the case that customers:

◯ Don't desire to decide the test results criteria. The laboratory will report according to the Test Report Criteria (No. 11)

◯ Desire to decide the test results criteria. The test results will be reported in accordance with the guidelines provided. However, **it must be samples that are accredited for the laboratory**.

11 **Test Report's Criteria**

1. Reporting of *In Vitro* Cytotoxicity Test

1 Qualitative evaluation: The achievement of a numeric grade greater than 2, based on below table, is considered a cytotoxic effect.

Table - Qualitative morphological grading of cytotoxicity of extracts

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmatic granules, no cell lysis, no reduction of cell growth
1	Slight	Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable.
2	Mild	Not more than 50 % of the cells are round, devoid of intracytoplasmatic granules, no extensive cell lysis; not more than 50 % growth inhibition observable.
3	Moderate	Not more than 70 % of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50 % growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers.

2. Quantitative evaluation: Reduction of cell viability by more than 30 % is considered as a cytotoxic effect.

Reference : ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

2. Reporting of *In Vitro* Hemolysis Test

Hemolytic Index above Negative Control	Reaction Level
0-2	No reaction
2-5	Slight reaction
>5	Severe Reaction

Reference : ASTM F756-13:2019 Standard Practice for Assessment of Hemolytic properties of Materials

3. Reporting of Bioburden Testing

Grade	Reaction Level	Characteristic / Conditions
-	No microorganism observed	No microorganism is observed on the medium after culturing with the test sample.
+	Microorganisms observed	Microorganisms are observed on the medium after culturing with the test sample.

Reference : ASTM D3516 Standard Test Methods for Ashing Cellulose

4. Reporting of Bioburden Testing with Identification

Test Result	Characteristic / Conditions
Types of microorganisms	The types of microorganisms that are identified on the medium after culturing with the test sample are categorized by genus.
Number of microorganisms	The number of microorganisms that grew on the medium after culturing with the test sample.

5. Reporting of Sterility Testing

Grade	Reaction Level
-	No microorganism observed
+	Microorganisms observed

Reference : ISO 11737-1: 2018 Sterilization of medical devices - Microbiological methods – Part 1: Determination of a population of microorganisms on products AMENDMENT 1			**Reference**: ISO 11737 – 2 :2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process	
6. Reporting of Susceptibility Test by means of Agar diffusion			**7. Reporting of Susceptibility Test by means of Broth dilution**	
Grade	**Reaction Level**	**Characteristic / Conditions**	**Test Result**	**Characteristic / Conditions of Cultured Cell**
-	No inhibition zone	No inhibition zone is presented around the test sample that was placed on the medium.	MIC	The lowest concentration of the sample that can inhibit the growth of microorganisms.
+	Slight inhibition zone	Inhibition zone is presented around the test sample that was placed on the medium.	*MIC: Minimum inhibitory concentration **Reference** : CLSI M07 10th edition: 2015 Methods for dilution antimicrobial susceptibility tests for bacteria that Grow aerobically	
Reference : CLSI M02 13th edition: 2018 Performance standards for antimicrobial disk susceptibility tests				
8. Reporting of *In vitro* Skin Irritation Testing				
Mean tissue viability is ≤ 50% in at least one extraction vehicle			Irritant (I)	
Mean tissue viability is > 50% in at least two extraction vehicles			Non-irritant (NI)	

Notes

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(If it is requested to test on samples with abnormalities or deviation from specified conditions, there will be a statement or a disclaimer – for example, "This report is outside the scope of ISO/IEC 17025:2017", in the test report.

Sender ……

(……)

Date……

Receiver ……

(……)

Date……

Laboratory Manager ……

(……)

Date……