**TECHNICAL SERVICE GUIDE**

Customer Name: Phone/Fax:

Add**ress** :

**Distributor: Essence Medical INC / KOREA** Contact :

Purchased Date : Originated by:

In order for us to initiate an investigation on your behalf, we require more information in order to process the complaint.  If you could please provide us with answers to the following critical questions, it would be appreciated.  This is what we need to know first to ensure patient care:

(YES or NO as required by FDA)

* Was there a death involved?
* Is it life threatening?
* Did it result in permanent impairment of a body function or permanent damage to a body structure?
* Did it necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure?

In addition, we need the following information in order to complete our documentation of this complaint and provide the information necessary to ensure an effective investigation:

\* Product Name:

\* Product Part #:

\* Product Lot #:

\* Expiration Date:

*\*Please know that you can also write “N/A” as “not applicable" if a question does not apply to your situation. \**

1.  What is this device being used for (Treatment, Diagnosis, or Research)?

2.  Has this been observed previously in the past 3 years?

3.  Is this being run on an automated system or manually?

4.  If being run on an automated system, what is the instrument (Brand and Model)?

5.  If being run on an automated platform, when was the last date of maintenance for the instrument?

6.  What was the method of retrieval?

7.  What was the antibody incubation time and temperature?

8.  What detection system was used?

9.  Were there any other ancillary or options used (blockers, washes, amplification, etc.)?

10.  What was the control tissue used and was it reactive for IHC?

11.  What species is the control tissue from?

12.  Was the control tissue internal or purchased and if purchased from where did you get this?

13.  Was this also run on any patient tissue and if so, what was the patient tissue and was it on human tissue?

14.  If internal tissue was used, how was it processed (fixation, bake time, etc.)?

15.  Please include any protocol summary, photos of staining, run reports, or any other pertinent information.

16.  Please describe the problem and add any details that we should know: