This article is a summary of a lecture given by Nobuyoshi Sato on features of the ATP+AMP Swab Test at a luncheon seminar* of the 76th Japan Gastroenterological Endoscopy Technicians Society on May 14 at Osaka International Convention Center (Grand Cube Osaka). Examples of use of the ATP+AMP Swab Test for endoscopes presented in the seminar are given in the Appendix.

* Co-hosted by Johnson & Johnson K.K. and Kikkoman Biochemifa Company

1. Overview of the ATP+AMP Swab Test

(1) “Cleaned” is not the same as “clean”

I will first talk about the basic and practical aspects of the ATP+AMP Swab Test (which I will refer to as the ATP Test) and discuss how this test is helpful for verifying the cleanliness of gastrointestinal endoscopes in clinical practice.

Briefly, the ATP+AMP Swab Test provides a simple and rapid evaluation of the cleaning efficacy. Specifically, anytime and anywhere, anyone can use this test to simply and rapidly (approx. 10 s) confirm whether an object or site that should be clean is actually clean.

Cleaning and wipe-off are very important operations to prevent accidental infection in healthcare facilities. With regard to hand hygiene, medical personnel understand that hand washing is the primary countermeasure against nosocomial infection. In environmental hygiene, hygiene control is important on frequently touched surfaces, while in cleaning of a reused medical device, thorough cleaning is the most important task for complete sterilization. Workers in charge of meals in hospitals understand that hygiene control of hands and cooking equipment is extremely important to prevent food poisoning.

These issues raise the question of how can personnel in charge of cleaning of gastrointestinal endoscopes confirm whether an endoscope is really clean after primary cleaning by manual cleaning. Can conditions that seem clean be validated to be truly clean? How can the cleanliness of parts that cannot be observed visually (e.g., inside endoscope channels) be validated? “Cleaned” and “wiped-off” are not always equal to “are clean” and “are wiped off”, and validation of cleanliness is needed. This is the value of the ATP+AMP Swab Test.
2. Assessment of the cleanliness of an endoscope

(1) Importance of preliminary cleaning of the endoscope

It is important to clean a used endoscope by hand before plac-
ing it in an automated washer or disinfection equipment. Many public documents specify the importance of preliminary cleaning and verification of the cleanliness level after cleaning.

For example, the Japan Gastroenterological Endoscopy Technicians Society issued a reminder document about spreading of carbapenem-resistant Enterobacteriaceae (CRE) by duodenoscopes in March 2015. This document indicated [1] determine ATP as an indicator for the cleanliness of a flexible endoscope; and [2] conduct culture tests for general bacteria on the surface and biopsy channel of endoscopes and equipment randomly once a year.

The 2012 Guidelines for Cleaning Assessment of the Japanese Society of Medical Instrumentation specify that it is important to degrade and remove attached materials as much as possible by cleaning for complete sterilization in “Article 1. Importance of cleaning, Part I Rating of cleaning assessment” and recommend ATP as an indicator for cleaning assessment. The 2015 Guidelines for Sterilization Validation at Medical Sites of the same Society proposed ATP measurement as a method of cleaning assessment.

The 2015 Guidelines for Sterilization Validation at Medical Sites also suggest that cleaning and disinfection may not be sufficient if a heavily contaminated endoscope is not initially cleaned before automated endoscope reprocessor (AER) cleaning, in “4.1.5 Establishing cleaning/disinfection conditions, in 4. Validation of endoscope cleaning/disinfection equipment and daily control.”

(2) Importance of “history management” of cleaning operations

In “4.1.7 Daily monitoring and control, in 4. Validation of endoscope cleaning/disinfection equipment and daily control”, it is stated that the cleaning/disinfection conditions should be confirmed and recorded as each process is completed, and that results are recorded to maintain process control. This shows the importance of “history management” in a cleaning operation.

In the Multisociety Guidelines on Infection Control of Gastrointestinal Endoscopes, revised version (2013), it is stated that “a definite disinfection effect requires cleaning of the outer surface of scopes, attachments and suction/biopsy channels at a high cleanliness level; to maintain the cleanliness level, it is preferable to check the level of current cleaning procedures in each facility, perform more effective cleaning, and record and store the date, time, patient’s name, endoscope no., name of the person in charge, automated endoscope washer/disinfection equipment no., concentration of disinfectant, and operating conditions of the automated endoscope reprocessor; a handwritten record is allowed, but commercial software specific to the record is easy to use; and history management corresponds to unexpected conditions.” These statements refer to preliminary cleaning and cleaning history management.

The ATP+AMP Swab Test permits simple and prompt assessment of the cleanliness of an endoscope at any time. Test results are shown as numerical ratings and are easy to use for history management.

(3) Test sites and procedures

Sites that are easily swabbed, including biopsy channel inlet, air/water channel, suction channel and tip, are wiped off with LuciPac Pen, as shown on the left side of Photograph 2.

For sites that LuciPac Pen cannot reach due to the thick cotton bud (e.g. inside the channel), LuciPac LS with a 40-cm cotton bud (diameters: 2.8 and 3.2 mm) is available, as shown on the right side of Photograph 2.

(4) What is the optimal cleanliness indicator?

We assessed the appropriate cleanliness indicator for a gastrointestinal endoscope using three methods: the ATP+AMP Test (Lumitester PD-30), protein assay (Bradford assay) and microorganism detection (TSA media) in Kikkoman General Hospital (Director: Yoshio Kubota, 129 beds, Noda, Chiba).

The swabbed site was inside the endoscope channel. A long cotton bud was inserted into the tip and then withdrawn. The tim-
ing of sampling was [1] before bedside cleaning (i.e., immediately after endoscopy), [2] after bedside cleaning and manual cleaning (i.e., after brushing), and [3] after automated washing.

[1] Upper gastrointestinal endoscope

Figure 4 shows the relationship of the ATP+AMP level with the viable cell count in an upper gastrointestinal endoscope. Samples with a high cell count are likely to have high ATP+AMP. However, before bedside cleaning (immediately after using the endoscope), high RLU* values in the ATP+AMP Swab Test were found, but the cell count was “not detected” in several samples. These results indicate that measurement of the viable cell count alone can overlook contaminants other than microorganisms.

Figure 5 shows the relationship of the ATP+AMP level with the protein level in an upper gastrointestinal endoscope. Before bedside cleaning (immediately after using the endoscope) high RLU* values were found in the ATP+AMP Swab Test, but protein level were close to detection limit.

These results show that use of microorganisms or proteins as an indicator for the cleanliness level may overlook insufficient cleaning.

[2] Lower gastrointestinal endoscope

A similar examination was conducted for a lower gastrointestinal endoscope (Figures 6 and 7). Similarly to Figures 4 and 5, samples with a high viable cell count are likely to have high ATP+AMP levels. No sample with a high viable cell count had a low ATP+AMP level. The ATP+AMP Swab Test was more sensitive than the protein detection method.

* RLU: Relative light unit (a specific unit used in the ATP Test)
* The results for the upper gastrointestinal endoscope were presented at the 88th Congress of the Japanese Society of Medical Instrumentation (June 7, 2013) and those for the lower gastrointestinal endoscope were presented at the 90th Congress (May 30, 2015).

(5) Rationale for setting a benchmark value

We recommend 100 RLU or less as the benchmark value in the ATP+AMP Swab Test for endoscopes.

Photograph 3 shows microscopic observation of a stainless steel plate with attached blood and RLU values measured by the ATP+AMP Swab Test. Blood was grossly observed on this plate and the value of the ATP+AMP Swab Test was at the upper limit (999,999 RLU) for the measurement instrument. After cleaning this sample a little (Photograph 3: after cleaning [1]), blood was still visible and the test value was still extremely high (21,881 RLU). After the plate was cleaned such that no residue was visible macroscopically (Photograph 3: after cleaning [2]), the value decreased markedly to 375 RLU. The sample was further cleaned until no residue was detectable microscopically (Photograph 3: after cleaning [3]), and the value further decreased to 35 RLU. These results indicate that a contaminant will not be detectable with a microscope if the

* Shown after conversion to the emission level determined by the common testing method.
* Emission amount (ATP+AMP): Less than the detection limit (73.5 RLU) is shown as half (36.7 RLU) of the detection limit.
* Protein: Less than the detection limit (0.653 µg) is shown as a half (0.326 µg) of the detection limit.

* Shown after conversion to the emission level determined by the common testing method.
* ATP+AMP: Less than the detection limit (73.5 RLU) is shown as half (36.7 RLU) of the detection limit.
* Protein: Less than the detection limit (0.653 µg) is shown as a half (0.326 µg) of the detection limit.

Figure 4: Relationship of ATP+AMP level with viable cell count in an upper gastrointestinal endoscope

Figure 5: Relationship of ATP+AMP level with viable cell count in an upper gastrointestinal endoscope
A sample is cleaned until a test value of 100 RLU or less is achieved. Figure 8 shows the relationship between the number of bacteria and the level of ATP+AMP in different environments. This figure shows a small number of bacteria are present at measurements of 100 RLU or less at many sites. This is one reason why 100 RLU is the recommended benchmark value, but 100 RLU may not always be the best benchmark value. We recommend investigation of current RLU values at a facility, and it is good to start with a slightly higher benchmark value. However, after ATP+AMP Swab Tests are conducted several times, the attitude of staff towards cleaning will improve or cleaning procedures will be revised, leading to a step by step decrease in values and achievement of the target 100 RLU value.

(6) Conclusion

Cleaning is an extremely important operation to ensure thorough disinfection. I hope that the ATP+AMP Swab Test will be used to prevent problems caused by insufficient cleaning.