180

160 140

100

80

40



FIGURE. Microorganisms isolated from patients with nosocomial urinary tract infections.

care practices, and implementation of infection control measures.

A common exogenous risk factor for all of the organisms causing nosocomial UTIs was catheterization. Inadequate infection control measures comprise another likely contributing factor. Inappropriate disconnection of the catheter-collecting tube junction can favor infection<sup>7</sup> and may have been a risk factor in this hospital.

Exogenous risk factors related to Escherichia coli, enterococci, Staphylococcus aureus, and Staphylococcus epidermidis nosocomial UTIs and the association between infections by these organisms and Proteus species and specific patient care areas could not be compared with prior data because surveillance of nosocomial infection has not been performed in this hospital on a routine basis. These results could provide baseline data for future comparisons, perhaps for assessing the influence of interventions.

Contrary to prior reports emphasizing only *Klebsiella* as a more frequent cause of nosocomial UTI among diabetic patients,<sup>8,9</sup> diabetes mellitus was an endogenous risk factor for most pathogens in the current study.

The relative lack of independent risk factors for nosocomial UTIs with *Serratia marcescens* could be due to the small number of cases studied. Because only four cases of nosocomial UTIs were due to *Acinetobacter calcoaceticus*, a case–control study was not conducted for this pathogen.

The distribution of microorganisms causing nosocomial UTI among our patients was similar to those from reports from other countries. Identification of risk factors for infection by various organisms may allow future risk-adjusted comparisons of infection rates.

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# Assessment of a Novel Approach to Evaluate the Outcome of Endoscope Reprocessing

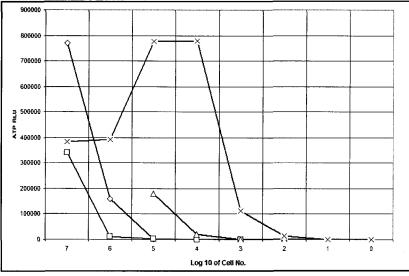
# To the Editor:

In the April issue of *Infection Control and Hospital Epidemiology*, Sciortino et al.<sup>1</sup> proposed a novel method to detect contamination of reprocessed endoscopes. Although bioluminescence could qualify as an economical method for this purpose, the study leaves several questions unanswered regarding the validity of this test.

Briefly, a portable luminometer system was used to compare 15 reprocessed endoscopes with microbiological culture, the currently accepted gold standard. Interpretative criteria for bioluminescence were established beforehand by comparing serial dilutions of bacteria with the assay under investigation. A total of 94 endoscopes were then examined only bioluminescence in different hv stages of reprocessing and declared sterile, clean, or contaminated. The results showed that some endoscopes without bacterial growth had negative results on Charm LUMinator-T (LUM-T) (Charm Sciences, Inc., Malden, MA) assay; reprocessing gradually decreased relative light unit (RLU) counts on most, but not all, endoscopes; and by bioluminescence, few of the reprocessed endoscopes could be declared sterile.

Since the early 1980s, many articles about bioluminescence have been published. The conclusions vary,<sup>2-6</sup> resulting mainly in the fact that bioluminescence has not evolved into a standard for validation of endoscope reprocessing methods. The current study was initiated as part of a broad investigation at one center in response to inadequate techniques for endoscope reprocessing. However, the authors claim the evaluation of a test as the main objective of their study.

The interpretative criteria derived from serial dilutions of bacterial suspensions, as shown in Figure 1 of the article (which appears on the next page), are suitable for the authors' intention, but some data are not reported. The results shown in the figure do not correspond to the numbers reported in the text. The lower limits of detecINFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY



**FIGURE.** Charm LUMinator-T (Charm Sciences, Inc., Malden, MA) analysis of adenosine triphosphate (ATP) relative light units (RLUs) versus actual colony-forming units or cell numbers for dilutions of cells dried on 100-cm<sup>2</sup> aluminum foil sheets. Triangle = *Candida albicans*; diamond = *Pseudomonas aeruginosa*; square = *Escherichia coli*; and  $\times$  = blood.

tion as read in the figure are  $10^6$  cells for *Pseudomonas aeruginosa* (vs  $10^5$ in the text) and  $10^2$  for blood cells (vs  $10^1$  in the text). Also, results for *Staphylococcus aureus*, mentioned in the Methods section, are not shown in the figure. Instead, data for *Escherichia coli* appear.

The cutoff values for sterile, clean, and contaminated are based on the results of this comparison only. and should be validated before implementation in clinical practice. With a lower limit of detection of 10<sup>6</sup> cells (eg, for E. coli), zero RLUs are used to declare an endoscope as being sterile, whereas in reality this could translate to anywhere between 0 and  $10^5$  cells. A correlation between cell counts and colony-forming units is not reported. The authors then compared their nonstandardized and unvalidated test with the gold standard (microbiological culture) in 15 samples that were selected only on the basis of bioluminescence results.

Comparisons of LUM-T results with Gram stain and culture are even more difficult to interpret because the sampling methods were completely different. Whereas sampling for the bioluminescence assay focused on the shank and the terminal 1 cm of the channel (which channel is not specified, nor is the type of endoscope), samples for cultures were taken from fluid used for flushing the inside of the endoscope. The results of cultures from sterile water in which the endoscopes were immersed are not reported. A correct validation would have performed both tests with the same sampling method in a blinded fashion on a random or consecutive sample of endoscopes and then compared the results using simple statistical tests for categorical and continuous variables. Therefore, the reported results represent a comparison of an unvalidated test method from the outside of the endoscope with a validated test method from the inside.

The "statistical analysis" performed to assess the cleaning and disinfection process shows only that consecutive cleaning, disinfection, and ethanol rinse reduced the amount of adenosine triphosphate (equaling cells) in most of the endoscopes tested. It is restricted to reporting mean RLU counts. None of these endoscopes were cultured for comparison.

Furthermore, several statements in the Discussion section of the article are misleading. First, the semiquantitative relationship between cell counts and adenosine triphosphate RLUs is a misnomer. Is this a way to express the fact that there is no quantitative correlation but a mere coincidence of positive results? Second, the argument that the lower limit of detection might miss skin contamination is euphemistic. Reprocessing of an endoscope with cleaning and highlevel disinfection should lead to an endoscope free of vegetative microorganisms regardless of their origin. This would be clearly missed by the test described. Third, the bioluminescence testing contributed in no way to the investigative steps described. The 100-fold greater sensitivity of this test compared with cultures is not supported by any data, and, accordingly, an appropriate literature reference is missing. No other study using bioluminescence to detect bacteria is cited in the reference list.

Bioluminescence has indeed been used as an audit tool to evaluate the efficacy of a cleaning system. An endoscope passing this test may still be contaminated. The authors' conclusion that "the system provided a rapid microbiological outcome monitor for the cleaning and disinfection process" may, although neither supported nor validated by this study, lead lawyers, judges, and hospital administrators to uncritical, inappropriate, and therefore harmful use.

The results of this study do not support the conclusions. Bioluminescence may be a surrogate marker, and this idea deserves publication. However, bioluminescence should be validated with the gold standard—microbiological cultures—with an appropriate sample size (eg, more than 250 endoscope cultures from different channels) before being recommended for use as a monitoring tool. Sensitivity and specificity results derived from such a study would be greatly welcomed by infection control professionals.

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## The authors reply.

Dr. Tietz and his associates state that the values in the figure do not correspond with statements in the text. In fact, they do. Although the lines of the graph may appear to reach zero in accordance with the statement by Dr. Tietz and his associates, in actuality,  $10^5$  Pseudomonas aeruginosa gave 2,135 RLUs, 106 Escherichia coli gave 1,369 RLUs, 10<sup>3</sup> Candida albicans gave 582 RLUs, and 10 red blood cells gave 14,274 RLUs. All were within the detectable range of the instrument. In addition to the quantitative data listed, quantitative studies were also performed with Staphylococcus xylosus, Erysipelothrix rhusiopathiae, Enterococcus durans, Streptococcus bovis, Streptococcus pyogenes, Staphylococcus aureus, and Streptococcus pneu*moniae*. Data from these studies were presented to the editor as a note in proof, but were omitted from the publication because they provided no additional significance to the data given.

We chose not to mislead readers into thinking that the bioluminescence assay is an exact quantitative measurement of colony-forming units. At least in our laboratory, we could not demonstrate precise quantitative numbers using this assay. The results we obtained for RLUs did, however, demonstrate approximate numbers of organisms on the logarithmic scale that best indicated high versus low microbial load.

The culture of endoscopes in this study included brushing the internal channels and the exterior of the endoscopes to dislodge any organisms. All were cultured or tested by gene probe technology. Therefore, the sampling for cultured endoscopes was the same as for the LUM-T assay with the exception that the entire internal channel was not sampled for the LUM-T assay. Five endoscopes that had negative results on the LUM-T assay were also cultured and had negative results. These five endoscopes served as the negative control, and if the sterile water used to rinse endoscopes had been contaminated, cultures would have revealed this. Therefore, the culture of the sterile water as suggested by Dr. Tietz and his associates is irrelevant.

We agree with Dr. Tietz and his associates that the cutoff values for sterile, clean, and contaminated were based on our observations, and we stated in the article that "other institutions may choose to set different limits based on their experiences with the LUM-T system."

High-level disinfection of endoscopes is a controversial issue. Highlevel disinfection does not equal sterility. Some argue that endoscopes should be rendered sterile and that only sterile endoscopes be used for patient care. Is this practical in the clinical setting?

Our findings showed that once endoscopes were reprocessed, they were not maintained in a sterile environment but rather a clean environment. Thus, our discussions with physicians indicated that some environmental contamination of endoscopes does reoccur prior to patient use. The level of recolonization then becomes a concern and an issue to be addressed. At what microbial load do we then deem an endoscope "improper for reuse?" How do we measure that in real time? Microbial culture of endoscopes requires days to weeks and is impractical. The bioluminescence assay can demonstrate contamination above that of normal skin flora and may prove to be the best rapid method available to demonstrate this phenomenon.

We have not stated or implied that a negative result on LUM-T assay equals sterility. The concept that not a single vegetative cell should exist on or inside the instrument before patient reuse is an idealistic one. We do not argue that conceptually sterility is the best practice, but rather that it is not the current standard. The question that then arises is whether it is feasible to create such standards. Unless standards are changed so that high-level disinfection imparts sterility and that sterility is maintained throughout storage and handling, we cannot ensure that infections will not arise from reprocessed endoscopes. Therefore, the decision to assume that all endoscopes are sterile because they have been high-level disinfected and to not monitor this process is misleading and possibly harmful.

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# Epidemic Parenteral Exposure to Volatile Sulfur-Containing Compounds at a Hemodialysis Center

#### To the Editor:

In the March issue of Infection Control and Hospital Epidemiology, Selenic et al. reported that an epidemic became manifest during 30 minutes beginning approximately 1 hour after reverse osmosis units were returned to the treatment loop during dialysis of 16 patients.<sup>1</sup> Their symptoms included chills, nausea, vomiting, hypotension, hypoxemia, tachypnea, fever, leukopenia followed by leukocytosis with a profound left shift, toxic granulations, and Döhle bodies. Two patients died and two had positive blood cultures, one for Citrobacter. Some water samples at the site contained excess endotoxin, and others contained excess viable aerobic bacteria.

The authors obtained samples 6 days after the dialysis center had been closed and the reverse osmosis unit had been sitting without water circulation. A "sulfur" odor was detected, which had been noted only once previously by an attendant, and the presence of four sulfur compounds, which the authors note may have been generated by growth of anaerobic bacteria in the inactive reverse osmosis unit, was detected by gas chromatography and mass spectrometry.

The authors stated that this was the first reported hemodialysis outbreak linked to sulfide exposure. They reviewed the toxicology of the sulfides they detected, given by non-