was remarkable for bilateral axillary adenopathy, marked wasting, xerosis, and firm, nonnodular hepatomegaly (18 cm span). Lymphocyte characterization revealed 700 absolute lymphocytes per mm^3 with a helper/suppressor T cell ratio of 0.1%. She was anergic. Serologic testing revealed an HIV ELISA value of 1.7 (positive test $\geq$ 1.3: Abbott Laboratories, Chicago, IL), however, Western blot analysis was interpreted as negative for p24 or gp41 on two occasions (see Figure, lab 3).

Because of the relationship between false positive ELISA testing and liver disease,[1] studies on a single serum were repeated by lab 3 and by two independent laboratories. HIV ELISAs were positive at each lab. Serum was tested by an unlicensed ELISA procedure that controls for nonspecific reactions with H9 cellular material (H9 exclusionary test, ENI).[1] Little reactivity was noted (HIV, 1.714; H9, 0.058), suggesting a true positive HIV ELISA. Indirect immunofluorescence was positive in both lab 1 and 2,[1,2] although nonspecific immunofluorescence was noted by lab 1 at low serum dilutions. Western blot assays revealed differences in both the number and intensity of bands observed by each lab, with resultant differences in the final interpretation. Lab 1 and 2 identified the sample as positive, based on the detection of gp41. Lab 1 also detected a faint p24 band. However, lab 3 interpreted the sample as negative.

These data illustrate that Western blot results are dependent on a number of variables. HIV antigen source, blocking buffers, and antigen detection methods used in current assays are not standardized. For example, the three assays represented in the figure used three different antigen sources and two antibody detection methods. Additionally, the stage of illness of the patient is also correlated with variations in Western blot banding patterns.[3] This patient with AIDS presented atypically with cholestatic hepatitis and cirrhosis. Until the H9 exclusionary test, immunofluorescence and additional Western blot data were available, physicians caring for the patient were reluctant to inform her of her likely prognosis and infectivity. Nevertheless, blood and secretion precautions were instituted. Our experience suggests that when patients develop clinical and laboratory findings suggestive of AIDS, the possibility of a false negative or false positive ELISA and Western blot test must be considered. The three Western blot assays in the figure not only illustrate the variations in test results that may be encountered by different laboratories, but also point for the need for improved confirmatory tests for HIV.

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Failure of Sterilization Process Indicators

To the Editor:

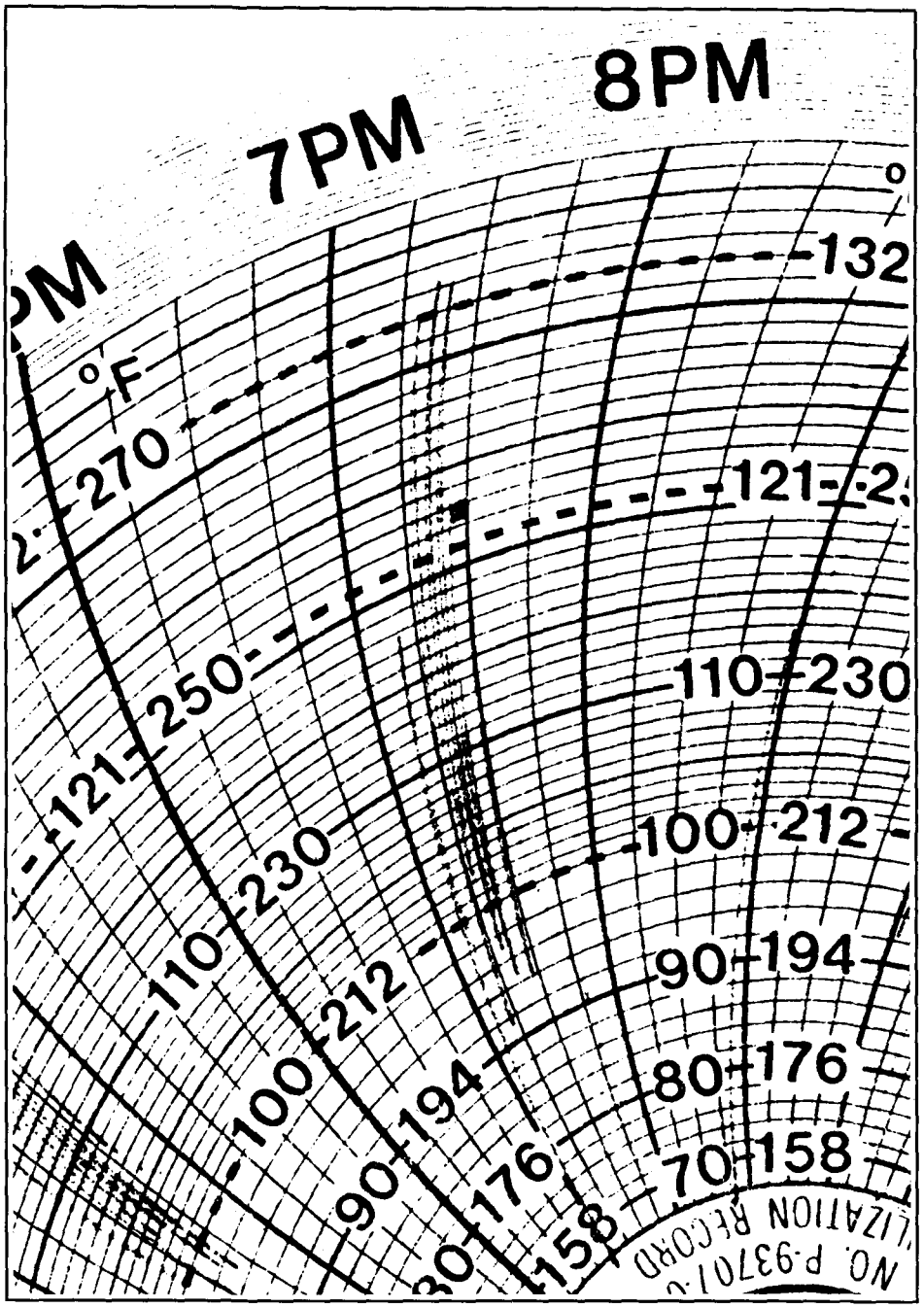
We wish to draw your readers' attention to a sterilizer operation incident that could be prevented by relatively simple engineering modification as well as by attention to process quality control.

The "hi-lo" steam pressure valve was changed to its "hi" setting on an AMSCO Eagle 2053 Vacamatic Sterilizer in preparation for 270°F cycles, but the temperature control was inadvertently left set at 250°F following gravity sterilization cycles. This 250° setting will affect chamber conditions during the sterilization phase of cycles, but not jacket or conditioning phase chamber temperatures. Time-temperature graph (Figure) indicates achievement of 270° for a brief time during conditioning phase of subsequent cycles, followed by return to 250°, as set, for the balance of exposure time. The short exposure time is suitable for 270°, not 250°. This flaw was overlooked by the sterilizer operator, but later detected on routine review by a department supervisor. After these graphs were examined, sterilization process indicators (VAC—Diack Inc.) in recalled packs were also examined and found melted. A weekly biological indicator (Spordi—AMSCO) test had also been run with the first of the implicated lots, and was reported as no growth during 7 days' incubation.

Subsequent recall did not retrieve all packs prior to use in surgery. One case was delayed while sets were changed; three other cases received linen packs or instrument sets from the improper cycle. Revision of central sterilizing department procedures to prevent recurrence involved requiring two signatures to release each sterilizer load, and modifying a sterilizer to provide an interlock preventing operation if settings for cycle temperature and the "hi-lo" steam pressure setting are inconsistent.

Sterilization was attained, as indicated by the biological indicator strips, in spite of improper control settings and the possibility of superheated steam. Two hundred fifty degree steam might have been superheated by jacket heat to maintain 270° (the peak temperature recorded by thermocouple and VAC) at the top of the chamber. Alternatively, time at higher temperature during the conditioning phase alone may have achieved sterilization. The former prospect is consistent with Savage's[1] findings, and either case underscores a wide safety margin in the time-temperature integrators and overkill sterilization cycles used by hospitals.

We investigated a possibility that higher temperatures achieved during the conditioning phase of the cycle were responsible for spore strip sterilization, not expecting that this exposure alone would achieve the 2



minutes at 270° in the center of packs reportedly required to sterilize spore strips. Two large linen packs were placed in an otherwise empty chamber, and the cycle interrupted after conditioning to evaluate process monitors in packs then exposed to a conditioning phase only. Spore strips from both packs, one placed high in the chamber and the other near the drain, showed no growth after 7 days. While this represents a "worst-case" situation for air entrapment in a high-vacuum sterilizer,[2] our brief experiment should not be interpreted as assurance of reliably achieving sterilization in abridged cycles.

This incident is cause for concern even though our process indicators, including spore strips, showed that sterilization was achieved in spite of error. Recall of defective packs may jeopardize a hospital's reputation. Delay or adverse patient outcome may result. One surgical procedure was delayed while new packs were obtained to replace those already opened. Three procedures were completed using packs from these lots. It would not be prudent to allow this vulnerability to persist.

Careful scrutiny of time-temperature graphs is of fundamental importance in a sterilization quality assurance program; this step must remain a critical priority in busy central supply departments. Need for timely review of findings by a second person was reinforced by our incident. Interlocking the cycle control and pressure control so that a sterilizer will not operate when control settings are inconsistent in this manner would add additional assurance of reliability. Sterilization process indicators placed in the centers of critical packs, a commendable practice, may not detect this type of error. We do not recommend relying on center-of-pack process indicators alone, and were compelled to recall critical packs upon noting the time-temperature graph results.

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