

# Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd<sup>1</sup>, M. Stirn<sup>1</sup>, R. Hofmann-Lehmann<sup>1</sup>, B. Riond<sup>1</sup>

<sup>1</sup>Clinical Laboratory, Department of Clinical Diagnostics and Services, Vetsuisse Faculty, University of Zurich, 8057 Zurich, Switzerland

## Abstract

The extent to which Swiss veterinary practitioners follow the guidelines for quality assurance of the American Society for Veterinary Clinical Pathology (ASVCP) for point-of-care (POC) testing is unknown. Thus, the aim of this study was to assess the availability, application, and quality management of POC analyzers in Swiss veterinary practices/clinics. For this purpose, we created an online questionnaire on laboratory equipment, quality management, and biosafety, which all members of the Society of Swiss Veterinarians (GST) were invited to complete. In total, 192 clinics/practices participated, of which 69% had automated POC analyzers, mainly for clinical chemistry (99%) and/or hematology (86%). Sample analyses and equipment maintenance were mostly performed by veterinary technicians (81% and 68%, respectively). Reference intervals were adopted from manufacturers (80%) or literature (17%). The results showed that most participants perform basic internal quality control (chemistry: 75%; hematology: 86%), and many use at least two levels of quality control material (47%–48%). Controls are mostly run once a month (chemistry: 36%; hematology: 35%) or  $\leq 4$  times/year (36% and 25%). Only three clinics/practices reported participation in an external quality assessment program; comparative testing was more common (chemistry: 42%; hematology: 52%). Only one-quarter of the participants stated that they make use of the data generated through internal and external quality control measures. In conclusion, POC analyzers are widely available in Swiss veterinary clinics/practices, and internal quality control is performed to some extent. However, quality assessment and management and biosafety awareness and measures need to be improved, ideally with the support of clinical pathologists.

**Keywords:** biosafety; diagnostic testing; point-of-care analyzers; quality assurance; quality control

## Untersuchung des gegenwärtigen Zustands der tierärztlichen patientennahen Labordiagnostik in der Schweiz: Verfügbarkeit, Anwendung und Qualitätsmanagement

Es ist nicht bekannt inwieweit Schweizer Tierärzte die Richtlinien zur Qualitätssicherung der American Society for Veterinary Clinical Pathology (ASVCP) für Point-of-Care-Tests (POC) einhalten. Ziel dieser Studie war es daher, die Verfügbarkeit, Anwendung und das Qualitätsmanagement von POC-Analysegeräten in Schweizer Tierarztpraxen/-kliniken zu untersuchen. Zu diesem Zweck wurde ein Online-Fragebogen zu Laborgeräten, Qualitätsmanagement und biologischer Sicherheit an alle Mitglieder der Gesellschaft Schweizerischer Tierärzte (GST) versandt.

Insgesamt nahmen 192 Kliniken/Praxen teil. 69% hatten automatisierte POC Analysegeräte, dies hauptsächlich für die klinische Chemie (99%) und/oder Hämatologie (86%). Probenanalysen und Gerätewartung wurde überwiegend von Veterinärmedizinerinnen durchgeführt (81% bzw. 68%). Referenzintervalle wurden von Herstellern (80%) oder aus der Literatur (17%) übernommen. Die Ergebnisse zeigten, dass die meisten Teilnehmer eine interne Qualitätskontrolle durchführten (Chemie: 75%; Hämatologie: 86%) und mindestens zwei Qualitätskontrollmaterialien (47%–48%) verwendeten. Die Kontrollen wurden meistens einmal im Monat (Chemie: 36%; Hämatologie: 35%) oder  $\leq 4$ -mal pro Jahr (36% und 25%) durchgeführt. Drei Kliniken/Praxen meldeten die Teilnahme an einem externen Qualitätsbewertungsprogramm; Vergleichstests waren häufiger (Chemie: 42%; Hämatologie: 52%). Ein Viertel der Teilnehmer nutzten die durch interne und externe Qualitätskontrollmaßnahmen generierten Daten. Zusammenfassend, POC-Analysegeräte sind in Schweizer Tierkliniken/-praxen weit verbreitet und interne

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Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

Qualitätskontrolle werden teilweise durchgeführt. Qualitätskontrollen und Management, sowie das Bewusstsein und die Maßnahmen für die biologische Sicherheit müssen verbessert werden, idealerweise mit Unterstützung von klinischen Pathologen.

**Schlüsselwörter:** Biologische Sicherheit; diagnostische Tests; Point-of-Care-Analysegeräte; Qualitätssicherung; Qualitätskontrolle

## Introduction

The constant invention and improvement of laboratory equipment has led to the development of a wide selection of complex analyzers for point-of-care (POC) testing. Veterinarians are increasingly offering extensive and versatile on-the-spot clinical diagnostics, and in-clinic testing is gradually overtaking the use of central laboratories for routine diagnostics. POC testing has some advantages, such as shorter intervals between sample collection, greater availability of the results, and the faster implementation of therapy. The American Society for Veterinary Clinical Pathology (ASVCP) also lists smaller sample volumes, enhanced patient monitoring, shortened hospital stays and independence from laboratory opening hours as potential advantages of POC testing.<sup>4</sup> Evidently, veterinarians need to be able to rely on the results from their in-clinic analyzers to prevent misdiagnosis and mistreatment. Quality in-house laboratory medicine is advertised by many manufacturers; however, when scrutinized closely, the accuracy and precision of POC analyzers are, in fact, rarely adequately tested<sup>6</sup>, and their performance, if trialed, can be moderate to questionable.<sup>21,22</sup>

External quality assessment and internal quality control are important components of quality management in laboratory medicine. Internal quality control makes use of control material of known concentrations, which is measured on-site at predetermined intervals with established limits for acceptable results. External quality assessment (also known as proficiency testing) is organized by an outside party and entails the comparison of numerous instruments using the same method. In human, but not in veterinary medicine, there are statutory regulations concerning quality assessment and quality control and the qualifications of the staff performing POC testing.<sup>17</sup> Veterinary practitioners are currently free to make diagnostic decisions based on test values without validation of the results from analyzers which have not been maintained or controlled, and the personnel does not need specific laboratory training.<sup>20</sup> In the publication of Mitzner in 2002, it was reported that veterinary medicine had come a long way, e.g., in terms of surgical techniques or therapeutic procedures; however,

the development of quality control and assessment for veterinary laboratory testing had been widely neglected. Accordingly, it was remarked, "It's time for in-house quality assurance".<sup>19</sup> Over 15 years later, however, this remains a major issue that still needs to be solved, according to several more recent studies.<sup>6,10</sup>

The ASVCP has set up guidelines for quality management, which outline minimal standards for POC laboratories regarding the implementation and frequency of maintenance, quality control, and assessment as well as recommendations for non-statistical quality control (e.g., a manual blood count to verify automatized results).<sup>4</sup> However, results from an international study show that only a minority of the practices follow these guidelines.<sup>6</sup> Possible reasons for this finding are the scarcity of the topic in veterinary curricula,<sup>4</sup> the failure of manufacturers to emphasize the importance of quality management,<sup>16</sup> and the veterinary practitioners' apparent unawareness of how to enforce effective protocols. Moreover, the quality control and assessment of POC analyzers are cost-intensive, increasing the expenses of the analyses.

Manufacturers of POC instruments have significantly reduced the chances of errors in the analytical and post-analytical phases of POC testing through comprehensive improvements of the devices,<sup>13</sup> such as the development of internal quality control mechanisms and electronic transfer of data. Nonetheless, it is still crucial to increase the awareness of veterinary practitioners to ensure higher POC testing quality. Additionally, clinical pathologists, as experts on the subject, should be consulted for guidance concerning the quality of laboratory medicine.<sup>9</sup> The results from a survey of human POC facilities in Norway, where a governmental quality management program had already been implemented, showed that feedback and guidance from a designated outside party were appreciated by the practitioners and that interest and awareness were generally enhanced.<sup>23</sup> Following examples in the United States, where laboratories are able to get accreditation for fulfilling certain quality standards (e.g., those of the American Animal Hospital Association, AAHA), the possibility of acquiring a certificate of the SVVLD (Swiss Association of

Veterinary Laboratory Diagnostics) and/or GST (Society of Swiss Veterinarians) could lend further motivation to upgrade quality management of POC testing in Swiss veterinary clinics and practices.

The aim of this study was to assess the current situation in Swiss veterinary facilities with POC laboratories using an online survey. Points of interest were the types of analyzers used and their providers, the qualification of the personnel conducting diagnostic tests, the handling of equipment maintenance as well as biosafety precautions, and the running of quality assessment and control. It was hypothesized that there would be a discrepancy between what is professed in the ASVCP guidelines and the current situation in veterinary in-clinic laboratories in Switzerland.

## Materials and Methods

### Subject Group

In order to test the hypothesis, a questionnaire was created and made available to all members of the Society of Swiss Veterinarians (GST). All kinds of veterinary clinics and practices using POC analyzers were included in the survey.

### Questionnaire

A questionnaire with 24 questions (Appendix 1) grouped into four subtopics, i.e., demographics, laboratory equipment, quality management, and biosafety, was developed in German, tested on a group of volunteer veterinarians, translated into French and Italian, and then made available online from September to November 2017 via an online survey provider.<sup>15</sup> The multiple-choice questionnaire was filled out anonymously, and participants could skip questions or fill in individual remarks if their preferred answer was not provided. It was possible to temporarily abandon the questionnaire and then resume it later from the same position.

Demographic inquiries included questions about the type of clinic/practice, as well as the type of veterinarians who work there (e.g., with *Federatio Veterinaria Helvetica*, FVH, GST specialization title; *Fachtierarzt/Fachtierärztin* or college diplomat). Since the term “clinic” is not protected in Switzerland, the designation may be made by the respective establishments. Questions about laboratory equipment evaluated details regarding the types of instruments used, the distributors or manufacturers, instrument handling (e.g., maintenance), and the personnel responsible for laboratory diagnostic procedures; questions regarding quality management were focused on internal quality control and external quality assessment as well as non-statistical

quality control; biosafety questions concerned matters of hygiene and biosafety.

### Descriptive statistics

Results were collected online<sup>15</sup> and exported to Excel (Microsoft Excel mac 2011) at the end of the three-month survey period. The collected data were analyzed in an exclusively descriptive manner. If a question allowed for multiple answers, the results were described in fractions but not percentages, since the total would otherwise exceed 100%. Participants who did not provide answers beyond the demographic questions were excluded from further analyses. Answers were excluded from calculations if they were contradictory. If two coinciding answers were given, e.g., reporting the use of two, as well as three, levels of quality control material, the highest value was chosen for the calculations, since the author concluded that the use of three levels inevitably also included the use of two levels of material.

## Results

### Demographics

The number of participants completing questions gradually diminished throughout the questionnaire, since partakers either skipped questions or quit the survey altogether. Other participants were forwarded to the section concerning biosafety and hygiene management because they did not own automatized laboratory analyzers. Around 30% (222) of the estimated 720 contacted practices visited the online questionnaire, although this count also includes individuals who clicked to start the survey but did not answer any of the questions. In total, the answers of 192 participants were included, but the number of responses for each question varied considerably (between 87 and 192 answers; Table 1).

Over two-thirds of the veterinary facilities surveyed were either small- or mixed-animal practices (137/192, 71.5%). Veterinarians with a certified specialization (diplomate status and/or FVH title) were present at 30% (57/189) of the sites.

### Analyzers and personnel

The majority (133/192; 69%) of the participants reported access to automatized POC laboratory equipment, suitable for veterinary samples; this included analyzers for clinical chemistry (99%) and hematology (86%), while instruments for coagulation (12%) and blood gas analyses (9%) were less common. Urinalysis was performed in 87% of the practices. Most practices reported conducting  $\leq 20$  analyses per week in clinical chemistry (95%), hematology (95%), and urinalysis (93%), and  $\leq 5$  tests in coagulation and blood gas analysis (90%).

Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

**Table 1:** Demographic information of the veterinary clinics/practices participating in the online survey on veterinary point-of-care testing in Switzerland.

	Number (%)
<b>Language of Questionnaire (n = 192)</b>	
German	157 (81.8)
French	31 (16.1)
Italian	4 (2.1)
<b>Type of Clinic (n = 192)</b>	
Small Animal Clinic	23 (12)
Small Animal Practice	84 (43.8)
Livestock Clinic	5 (2.6)
Livestock Practice	7 (3.6)
Horse Clinic	4 (2.1)
Horse Practice	3 (1.6)
Mixed Clinic	9 (4.7)
Mixed Practice	53 (27.6)
Other	4 (2.1)
<b>Cases (n = 191)</b>	
Referral	9 (4.7)
Primary	174 (91.1)
Both	6 (3.1)
Others	2 (1)
<b>Specialization of Veterinarians (n = 189)</b>	
American or European College	10 (5.3)
FVH Title	37 (19.6)
Both	10 (5.3)
Other	20 (10.6)
No Specialization	112 (59.3)

Mostly, veterinary technicians were reported to be responsible for blood sample analyses (108/133) as well as equipment maintenance (88/129). Another question inquired about the division of responsibilities – only 6% of the participants (8/132) stated they had designated laboratory personnel who were primarily occupied with laboratory diagnostic work. The majority of the participants (79/122) stated that instrument maintenance was performed at least once a month. Since maintenance frequency can vary between different types of instruments, multiple answers were allowed. Individual answers such as “according to the manufacturer’s instructions” or “whenever needed” gave no information on the frequency and were not included in the calculations.

Most of the participants reported that their manufacturers provide various support services (108/114; 95%). A telephone helpline was used by 85% of respondents (97/114). Most participants stated that they use technical support on-site (76%, 87/114), and 65% (68/114) reported using the quality control material supplied by their manufacturer for internal quality control. In 30% (34/114) of the practices/clinics, staff members had vis-

**Table 2:** Characteristics of veterinary point-of-care analyzers used by the participants of the online survey on veterinary point-of-care laboratories in Switzerland.

Analyzers	Number
<b>Clinical Chemistry</b>	
Idexx Catalyst	33
Idexx Vetest	22
Idexx Unspecified	7
Abaxis Vetscan	20
Fuji Dri Chem	14
Arkray Spotchem	2
Other	13
Total	111
<b>Hematology</b>	
Idexx Lasercyte	18
Idexx Procyte	17
Idexx QBC	5
Idexx Unspecified	9
Scil vet Vet ABC	21
Sysmex Poch 100i	3
Other	15
Total	88
<b>Urine analysis</b>	
Idexx Sedivue	1
Idexx UA Analyzer	1
Arkray urine analyzer	1
Siemens unspecified	1
Henry schein OneStepPlus	1
Arkray Aution Hybrid	1
Unspecified	11
Total	17
<b>Coagulation</b>	
Idexx Coag Dx	2
Idexx Unspecified	4
Abbott iStat	1
Total	7
<b>Blood gas analysis</b>	
Idexx VetStat	4
Idexx Unspecified	4
Abbott iStat	3
Siemens EPOC	1
Total	12

ited at least one instrument training session for their POC analyzer that was provided by the manufacturer. Idexx Laboratories analyzers were reported to be the most commonly used instruments by the participants for all diagnostic areas (Table 2).

Features for security measures have been integrated, by design, into many analyzers to reduce the occurrence of pre-analytical, analytical, and post-analytical errors.

According to the participants, the most commonly used features are the electronic transfer of results for clinical chemistry and hematology instruments (65%) and the mandatory insertion of patient information prior to testing (64%).

### Standard operating procedures

Standard operating procedures (SOP) were reported to be available in the participants' clinics/practices for blood gas analysis (92%, 11/12), clinical chemistry (89%, 117/131), hematology (89%, 102/115), and coagulation (88%, 14/16). They were less commonly available for urinalysis (68%, 78/115).

### Reference intervals

Reference intervals were most often adopted from manufacturers (88/110), and/or to a lesser extent, extrapolated from the literature (19/110). There were a few participants (23/110) who had validated the reference intervals before applying them to clinical use. Two participants had established their own reference intervals (2/110).

### Quality control and quality assurance

Internal quality control was predominantly performed on clinical chemistry instruments (75%, 76/101) and hematology analyzers (86%, 66/77). Most participants used two or more control material levels (Table 3). Controls were run once a day, once a week, once a month,  $\leq 4$  times/year, or whenever maintenance was performed or reagents were changed (Table 4). In some cases, controls were run after reagent changes or the performance of maintenance in addition to monthly or quarterly internal quality control.

The presence of specialists, as well as the "clinic" status, had little to no effect on the occurrence of quality control. There was, however, a connection between quality control management and the number of analyses con-

**Table 3:** Number of quality control material levels used by the participants of the online survey on veterinary point-of-care laboratories in Switzerland.

Quality control material	Chemistry (%)	Hematology (%)
$\geq 2$ Level	49 (48)	36 (47)
1 Level	14 (14)	18 (24)
Other	13 (13)	12 (16)
No quality control	25 (25)	11 (14)

**Table 4:** Frequency of the internal quality control performed by the participants of the online survey on veterinary point-of-care laboratories in Switzerland.

Frequency	Chemistry	Hematology
1x/Day	1	2
1x/Week	4	7
1x/Month	28	24
1x/Month +	1	3
$\leq 4$ x/Year	28	17
$\leq 4$ x/Year +	4	5
Maintenance or reagent change	12	10

Monthly and quarterly internal quality control combined with controls after maintenance and/or reagent changes are marked with +.

ducted per week—facilities with a higher turnover rate tended to perform more extensive internal quality control (Table 5).

In this study, very few veterinarians reported taking part in commercially available, external quality assessment programs for clinical chemistry (3/100) and hematology (2/83) analyzers, and none for instruments from any of the other diagnostic areas (urine: 0/28; coagulation: 0/8; blood gas: 0/11). As an alternative, practitioners reported the use of comparative testing (chemistry: 42/100; hematology: 43/83); for this purpose, they send samples to other clinics or reference laboratories to compare results. In addition, they use other means of external quality assessment that were not provided as an answer in the questionnaire (chemistry: 10/100; hematology: 8/83). Many of the participants stated that they

**Table 5:** The percentage of facilities of the online survey on veterinary point-of-care laboratories in Switzerland conducting internal quality control on their in-clinic analyzer, as well as frequency and number of levels of quality control material in relation to the number of analyses performed per week.

Analyses/Week	Number of participants performing internal quality controls (%)	% of participants using 1, 2, or 3 levels of control material			Frequency for conducting quality control in %		
		3 Levels	2 Levels	1 Level	Daily/Weekly	Monthly	Quarterly
Chemistry							
1–5	35/48 (73)	58	4	38	0	29	71
6–10	25/36 (69)	52	35	13	9	39	52
11–50	20/22 (91)	81	6	13	14	64	23
Hematology							
1–5	30/39 (77)	33	17	50	5	43	52
6–10	28/33 (85)	48	22	30	12	48	40
11–50	15/15 (100)	69	8	23	38	54	8

Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

do not perform any form of external quality assessment on their analyzers (chemistry: 46/100; hematology: 32/83).

Regular revision of the data generated through internal quality control and external quality assessment (e.g., Levey–Jennings charts, checking over time if measured values lie within the desired range) was reported by 26/104 of the respondents. Most of the participants (73/104) stated that they do not process their control data. In some cases (13/104), the owner relies on the manufacturer to monitor the control data and draw attention to worrisome tendencies or erroneous results.

### Testing of plausibility

Participants were asked what kind of non-statistical quality control methods they apply on their hematology analyzers. It was reported by 63% (55/87) of the participants that hematocrit results are compared to the capillary hematocrit while 60% (52/87) of the practices/clinics monitor automatized white blood cell differential counts with manual differentiation. Several participants with automatized instruments (17/98) stated that they prepare blood smears for (almost) every hematology sample, 55/98 at least when clinically indicated (e.g., values outside of the reference intervals), and 20/98 occasionally use smears as a control. About one-quarter of the participants (24/98) stated that they rarely prepare blood smears.

### Hygiene and biosafety management

Forty-nine percent (68/140) of the in-clinic analyzers in this survey were reported to be located in a separate room. Eating and drinking were reported to be forbidden in 51% (72/140) of the in-clinic laboratories. In most cases, the possibility of hand disinfection inside or near the laboratory was available (81%, 113/140), but only few reported that their laboratory provides a description for correct hand disinfection (16%, 23/140). Almost all the participants stated that the surface of their analytical workspace is easy to clean (94%, 132/140), but only much smaller number stated that there were displayed instructions on how to correctly clean and disinfect the workspace (13%, 18/140). Most of the participants reported using Kohrsolin® (95/138), soap (90/138), and/

or water (90/138) in different combinations, or alone, at various frequencies (Table 6). In most cases, laboratory equipment (e.g., centrifuges) is cleaned  $\geq 1 \times / \text{week}$  (69/138), while in some clinics/practices, the equipment is cleaned after every sample (5/138) or once a day (8/138). Some clinics/practices only cleaned equipment in the event of contamination (28/138).

Approximately half of the participants were aware that the material handled in their POC laboratory might be potentially infectious (46%, 64/140). Wearing gloves and/or lab coats for diagnostic tasks was reported to be mandatory in 43% (61/140) and 18% (25/140), respectively, of the in-clinic laboratories. Appropriate disposal of medical waste was reported to be organized in 49% (68/140) of the practices. By contrast, most of the participants stated that they discard pointed or sharp objects into non-penetrable containers (97%, 136/140).

## Discussion

To our best knowledge, this is the first study addressing the availability, application, and quality management of veterinary POC testing in Switzerland. The aim was to evaluate the adherence of current proceedings to existing guidelines (e.g., ASVCP guidelines).<sup>4</sup> The current study demonstrates that POC laboratories are common and well used in Swiss veterinary facilities for clinical chemistry and hematology. Although practitioners show promising efforts towards enhancing the quality of their in-house laboratories, most practices and clinics do not currently abide by the standards set by the ASVCP.<sup>4</sup>

Although the answer rate between questions varied noticeably, there was a minimum of 87 responses for every question to be evaluated. The answers of 192 participants were included. The partaking clinics and practices were considered to be representative regarding facility type and geographical spread (based on the number of questionnaires filled out in German, French, and Italian). The majority of the participants were from small- or mixed-animal practices, which reflects the distribution of veterinary facilities listed on the GST website<sup>1</sup> as well as the results from an international study on quality control management.<sup>6</sup>

POC analyzers, although also common, were reported to be less prevalent in Swiss veterinary practices (69%) than on an international scale, as shown in a study by Bell et al., where 92% of the participants had in-clinic laboratories.<sup>6</sup> This might be accredited to the size of the country and the consequential close proximity of many veterinary clinics and practices to central laboratories. Likely, this outcome is also related to the smaller size of the practices and the number of personnel when com-

**Table 6:** Frequency and means of cleaning of laboratory equipment in the clinics/practices participating in the online survey on veterinary point-of-care laboratories in Switzerland.

Frequency (138)	Water	Soap	Kohrsolin®
After every sample	41	28	30
In case of contamination	31	34	36
1×/Day	15	15	28
<1×/Day	15	27	20

Participants could choose multiple answers. Absolute numbers are given.

pared to the US, since it might be less costly for smaller practices to outsource diagnostic testing. The ASVCP advises veterinarians to consider the use of POC testing if the presence of an in-clinic analyzer would accelerate diagnoses as well as therapeutic measures.<sup>4</sup> As mentioned above, this might be less abundant in a densely populated country like Switzerland.

In accordance with the results from the Bell study, veterinary technicians were reported to be responsible for diagnostic analyses as well as instrument maintenance in the majority of the veterinary facilities in the current study.<sup>6</sup> The British Medicines and Healthcare Products Regulatory Agency recommends that the personnel handling laboratory diagnostics should be adequately trained and their competency regularly assessed.<sup>18</sup> The same is true for laboratory personnel in human medicine in Switzerland, where qualification and ongoing education must be recorded in individual personal dossiers.<sup>17</sup> During training, all operators should be made aware of the intended use, performance characteristics, limitations, and contraindications of the devices, and they should learn common troubleshooting to minimize errors. Only 30% of the participants stated that the person responsible for laboratory testing in their facility had completed at least one training on the use of their respective analyzers, made available by the manufacturer.

To promote the quality of laboratory diagnostics, the ASVCP recommends that SOPs be provided for every analyzer.<sup>4</sup> It is crucial that every person operating a particular analyzer performs every step of the analytic process in the same way every time. This recommendation seems to be well known since SOPs were reported to be provided in most of the practices for hematology (88.7%), clinical chemistry (89.3%), coagulation (87.5%), and blood gas analyses (91.7%) instruments, and in 67.8% of the practices performing urinalysis. Usually, if a particular facility provided a SOP for one type of machine, they also would provide one each for all the equipment within the facility, though the questionnaire did not enquire whether the SOPs were self-written or provided by the manufacturer. The fact that urinalysis is performed manually, rather than automatically, might explain why the use of SOPs for this type of analysis were far less common. However, written instructions should be provided regardless of the method.

The ASVCP states that reference intervals, should be created “de novo” or at least be validated, when adopted from a source.<sup>12</sup> For example, the results of at least 20 healthy individuals with a maximum of two results outside of the submitted reference intervals should be compared before the analyzer is put to clinical use.<sup>12</sup> The results of the current study showed that only a small

portion of the participants (23/110) validate the reference intervals, which means that almost 80% do not abide by the ASVCP guidelines on this point. However, these recommendations are not necessarily economical and feasible in smaller practices with a low number of samples. In such cases, it is reasonable for practitioners to ascertain that manufacturers provide reference ranges prior to equipment purchase and to instead adopt those reference intervals for clinical use. Accordingly, most of the participants (88/110) reported the use of reference intervals provided by the manufacturer. The ASVCP strongly advise against the use of published reference intervals.<sup>12</sup> Nonetheless, 19/110 participants acquire their reference ranges from the literature.

Internal quality control and external quality assessment are important elements of quality management and should be conducted at appropriate intervals. Currently, there are no governmental regulations concerning quality assessment and control in veterinary POC laboratories. Moreover, the veterinary curricula provide little to no education on quality management and the manufacturers often fail to inform their clients of its importance. In the current study, there seems to have been some confusion regarding the nature of quality assessment and quality control since a few participants gave contradictory answers. Five participants who stated they do not perform quality control also specified either how many levels of quality control material were used or the frequency at which it was conducted. Similar issues were raised in the Bell study,<sup>6</sup> where people had trouble, or failed, to distinguish between the two terms when asked to write respective definitions. This calls to attention the gaps in knowledge and need for education regarding quality management.

To generate adequate control data for internal quality control, it is recommended that at least two levels of control material be used<sup>16</sup> at no greater than weekly intervals.<sup>4</sup> Almost half of the participants reported the use of at least two levels of quality control material for clinical chemistry (49%) and hematology (48%) analyzers and are, therefore, in compliance with the first part of these recommendations. However, controls are rarely run daily or weekly on chemistry (6%) and hematology (13%) instruments. The results showed a correlation between the number of analyses conducted per week and the frequency at which internal quality control is performed. This seems logical, since facilities conducting only a few analyses per week (e.g., 1–5 analyses), would incur disproportionately high costs for weekly, or even daily internal quality controls. Nevertheless, a compromise must be found in such cases,<sup>14</sup> since neglecting quality assurance could lead to misdiagnosis and mistreatment, a risk that is unacceptable. The Australasian Association of Clinical Biochemists (AACB)

Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

published an implementation guide on POC testing, where they recommend a minimum of one control sample per month, ideally at a pathological level.<sup>3</sup> Even with these minimal standards, only some of the participants who said they performed quality control are in compliance (chemistry: 44%; hematology: 53%).

The ASVCP guidelines state that proficiency testing should be performed at least four times a year.<sup>4</sup> Almost none of the responding veterinary facilities reported taking part in commercial external quality assessment programs for clinical chemistry (3/101) and hematology (2/83) analyzers. This was not unexpected since providers of such programs do not generally target analyzers used in the POC environment and a corresponding peer group is not readily available. However, many of the participants send samples to reference laboratories or other clinics/practices for comparative testing (chemistry: 42/100; hematology: 43/83). While this method has some disadvantages, such as the comparison of different methods, it is viewed as an acceptable alternative by the ASVCP if the results are recorded and evaluated properly. A stable sample, tested and compared periodically, is needed to deliver sound information on instrument performance.<sup>4</sup> The data, generated by control runs, should be stored for two years.<sup>5</sup> They should also be reviewed regularly, checked for error flags, and be displayed in a graph to detect shifts or trends over time.<sup>4</sup> Although most of the participants confirmed that they store the control data, only 26/104 make regular revisions of the data and thus comply with the ASVCP guidelines.

For a long time, the occupational safety and health risks for veterinary staff were not considered to be equal to those faced by human health sector employees. Over recent years, this perception has been corrected somewhat due to the zoonotic nature of many emerging diseases.<sup>24</sup> Safety measures must be established, and veterinarians and technicians need to be aware of the potential health risk they are subjected to when handling samples, even within the POC environment.<sup>18</sup> The Swiss Ordinance about employee protection from risks related to exposure to microorganisms (SAMV), states that any facility performing clinical laboratory diagnostics (human and veterinary medicine) is bound by law to follow these precautions.<sup>8</sup> Alarmingly, less than half of the participants in the current study were aware of working with potentially infectious material in their in-clinic laboratory. Accordingly, the regulations concerning hygiene and biosafety, were reported to be occasionally neglected. Almost half of the participants of this study stated that eating and drinking is not forbidden in their POC laboratory. Also, wearing gloves or lab coats for analytic procedures is only obligatory in 43% and 18% of the practices. By contrast, the impor-

tance of hand hygiene appeared to be well known as many of the partakers (81%) reported the opportunity for hand disinfection inside or in the immediate proximity of the in-clinic laboratory.

Governmental regulations in Switzerland demand that clinical waste, including sharps, must be packed, labeled, and discarded according to their classification.<sup>7</sup> Veterinarians need to be aware that waste from POC laboratories may contain pathogenic microorganisms which are classified as group 3 organisms, according to the Federal Office for the Environment (e.g. rickettsia spp).<sup>11</sup> The Swiss Ordinance on Handling Organisms in Contained Systems. (“Einschliessungsverordnung”(ESV): Verordnung über den Umgang mit Organismen in geschlossenen Systemen) and the Swiss Ordinance about employee protection from risks related to exposure to microorganisms require that such waste needs to be inactivated before disposal as special waste.<sup>2,8</sup> Both ordinance assume that an autoclave is used for inactivation, although validated equivalent chemical methods of inactivation are also permissible. Furthermore, the ESV destines that diagnostic samples from class 2 activities can be disposed as special waste, but suitable transport containers have to be used and all containment measures need to be ensured to avoid danger to humans and environment. The presence of an in-clinic laboratory and the diagnostic handling of samples automatically places veterinary clinics and practices under these biosafety restrictions. This is in contrast with the situation where biological samples are only collected and not processed. However, this difference seems widely unknown. Less than half of the partaking clinics and practices (49%) in the present study reported discarding medical waste in a manner that complies with the current health and safety policy. On the other hand, the disposal of sharp objects is organized in an appropriate fashion in almost all the facilities (97%).

The preamble to the questionnaire stated that it should only be filled out by one person from each site; however, since the questions were answered anonymously, this could not be verified and represented a limitation of this study. Also, due to anonymity, contradictory or unintelligible answers could not be followed up and were therefore excluded, resulting in the loss of information.

## Conclusions

The status quo of quality management at Swiss POC laboratories is comparable to data collected in an international study conducted in the United States.<sup>6</sup> Nonetheless, it does not fulfill the requirements of the ASVCP guidelines. Also, the current state of biosafety measures and employee protection, as shown in this study, are not

always compliant to official Swiss regulations.<sup>8</sup> An apparent lack of a control authority for the biosafety aspect in the veterinary practice laboratory is an important reason for the described situation. Further efforts from the GST/SVVLD in collaboration with the Swiss authorities is highly recommended by the authors of this study. In addition, further education, on quality assessment and control as well as biosafety aspects, is needed. A greater prominence of this topic in the veterinary curricula and advanced training would contribute to increased awareness and knowledge concerning this matter. Additionally, it would be beneficial for manufacturers to provide their clients with the information and means for performing quality control and external quality assurance. It is important that users of POC analyzers know how and why they should perform quality assessment and control, and are informed about the costs associated with these procedures before purchasing POC equipment. The results of this study suggest that many of the participants are willing to perform quality control and assessment but are unsure how to proceed. Since knowledge and understanding of this matter are

limited, users of POC analyzers need simple implementation guidance. The comprehensive nature of the guidelines provided by the ASVCP might reduce their impact, while an easy-to-read quality management guide might prove to be more efficient for promoting in-house laboratory quality in veterinary medicine. In future, the accreditation of POC laboratories (e.g., accreditation awarded by the SVVLD and/or GST) performing quality control and assessment according to the appropriate standards might motivate and help owners of POC analyzers to implement a reasonable and feasible plan for quality management in their in-clinic laboratories.

Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

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## Enquête sur le statut des laboratoires vétérinaires aux points de service en Suisse: disponibilité, application et gestion de la qualité

On ignore dans quelle mesure les vétérinaires suisses respectent les directives d'assurance qualité de l'American Society for Veterinary Clinical Pathology (ASVCP) pour les tests au point de service (Point of Care, POC). Ainsi, l'objectif de cette étude était d'évaluer la disponibilité, l'application et la gestion de la qualité des analyseurs POC dans les cabinets/cliniques vétérinaires suisses. À cette fin, nous avons créé un questionnaire en ligne sur les équipements de laboratoire, la gestion de la qualité et la biosécurité que tous les membres de la Société suisse des vétérinaires (GST) ont été invités à remplir. Au total, 192 cliniques/cabinets ont participé, dont 69% avaient des analyseurs POC automatisés, principalement pour la chimie clinique (99%) et/ou l'hématologie (86%). Les analyses des échantillons et la maintenance de l'équipement ont été principalement effectuées par des assistant(e)s en médecine vétérinaires (81% et 68%, respectivement). Les intervalles de référence ont été fixés sur la base des indications des fabricants (80%) ou de la littérature (17%). Les résultats ont montré que la plupart des participants effectuent un contrôle de qualité interne de base (chimie: 75%; hématologie: 86%) et que beaucoup utilisent au moins deux niveaux de matériel de contrôle de la qualité (47%–48%). Les contrôles sont principalement effectués une fois par

## Indagine sullo status quo dei laboratori nelle sedi di cura veterinarie in Svizzera: disponibilità, applicazione e gestione della qualità

Non si era a conoscenza fino a che punto i veterinari svizzeri seguivano le direttive per la garanzia della qualità dell'American Society for Veterinary Clinical Pathology (ASVCP) per i test presso le sedi di cura (POC). Lo scopo di questo studio era quindi di valutare la disponibilità, l'applicazione e la gestione della qualità degli indicatori POC negli studi/cliniche veterinarie svizzere. A questo scopo abbiamo creato un questionario online sulle apparecchiature di laboratorio, sulla gestione della qualità e sulla sicurezza biologica, che tutti i membri della Società dei veterinari svizzeri (GST/SVS) sono stati invitati a compilare. In totale hanno partecipato 192 cliniche/studi, di cui il 69% ha automatizzato gli indicatori POC, principalmente per la chimica clinica (99%) e/o l'ematologia (86%). Le analisi dei campioni e la manutenzione delle apparecchiature vengono eseguite per lo più da tecnici veterinari (81% e 68%, rispettivamente). Gli intervalli di riferimento adottati provengono dai produttori (80%) o dalla letteratura (17%). I risultati hanno evidenziato che la maggior parte dei partecipanti effettua un controllo di qualità interno di base (chimica: 75%; ematologia: 86%), e molti usano almeno due livelli di materiale di controllo della qualità (47%-48%). I controlli vengono eseguiti per lo più una volta al mese (chimica: 36%; ematologia: 35%) o ≤

Investigation of the Status Quo of Veterinary Point-of-Care Laboratories in Switzerland: Availability, Application, and Quality Management

R. Zahnd et al.

mois (chimie: 36%; hématologie: 35%) ou  $\leq 4$  fois / an (36% et 25%). Seules trois cliniques/cabinets ont déclaré avoir participé à un programme externe d'évaluation de la qualité. Les tests comparatifs étaient plus courants (chimie: 42%; hématologie: 52%). Un quart seulement des participants ont déclaré utiliser les données générées par des mesures de contrôle de qualité internes et externes. En conclusion, les analyseurs POC sont largement disponibles dans les cliniques/cabinets vétérinaires suisses et le contrôle qualité interne est effectué dans une certaine mesure. Cependant, l'évaluation et la gestion de la qualité ainsi que la sensibilisation et les mesures en matière de biosécurité doivent être améliorées, idéalement avec le soutien de pathologistes cliniciens.

**Mots clés:** biosécurité, tests de diagnostic, analyseurs de point de service, assurance qualité, Contrôle de qualité

a 4 volte/anno (36% e 25%). Solo tre cliniche/studi hanno riferito di aver partecipato a un programma di valutazione esterna della qualità; i test comparativi sono stati più comuni (chimica: 42%; ematologia: 52%). Solo un quarto dei partecipanti ha dichiarato di utilizzare i dati generati attraverso misure di controllo della qualità interne ed esterne. In conclusione, gli indicatori POC sono ampiamente disponibili nelle cliniche/studi veterinari svizzeri e il controllo della qualità interno viene effettuato in una certa misura. Tuttavia, la valutazione e la gestione della qualità e la consapevolezza e le misure di biosicurezza devono essere migliorate, idealmente con il supporto di patologisti clinici.

**Parole chiave:** biosicurezza, test diagnostici, indicatori per sedi di cura, garanzia di qualità, controllo della qualità

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## Corresponding author

Martina Stirn  
Veterinärmedizinisches Labor  
Winterthurerstrasse 260  
8057 Zürich  
044 635 90 79  
E-Mail: mstirn@vetclinics.uzh.ch

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