WHY A CLINICAL PATHOLOGIST?

HOW TO SET UP A REFERENCE QUALITY LABORATORY

WHY WOULD YOU WANT TO?

- A reference quality lab will improve the confidence you have in your results. It will increase your sense of pride in your practice and you will be an innovator.
- This type of a lab will increase the confidence that your clients (particularly other practices) have in the quality of your work.
- It is a good marketing point for you as many of your pet owners have access to information regarding laboratory diagnostics (internet) and to tell them your instruments are the same/comparable to those used for their own laboratory testing improves confidence in your test results.
- Further the instruments are the same used in most Veterinary Colleges.
- From a profit standpoint, you will improve the bottom line.

In House testing also improves turnaround time for test results and thus answers for you clients.

HOW TO EXPLAIN WHAT I DO?

1. Determine the machines that will be worthwhile based on ease of use, preventative maintenance program, reagent availability
2. Determine machine costs
3. Get machines up and running, calibrations, determine performance, interferograms etc.
4. Prepare manuals that will cover all aspects of running these machines and outline all testing procedures so that all personnel will perform the same. Establish QA procedures and QC and train personnel in the interpretation of the QC. QA either tests the outcome or measures the precision/accuracy of the results.
5. Establish reference intervals for all the species; make these at least age related.
6. Train the personnel, and upgrade the existing personnel to the new procedures and instrumentation.
7. Work with the clinicians to explain test results, determine "critical" levels
8. Review hematology, perform cytology

So a clinical pathologist will provide:

-Machine knowledge

-Disease interpretation and correlation

-Training of personnel

-Establishing methodology

-Determining reference intervals

-Quality assurance – you identify conformance/noncomformance

-SOP's for the lab

-Non-statistical controls

-Statistical controls

CYTOLOGY AND HEMATOLOGY INTERPRETATION AND REVIEWS

There are no rules/regulations governing the testing and quality of machines for use in veterinary diagnostic labs or veterinary hospitals.

There are abundant rules and regulations that apply to machines used in human diagnostic laboratories and they all must have FDA certification and comply with GLP rules.

In most veterinary schools and in all veterinary reference laboratories the machines used to run the test are the human diagnostic lab equipment.

What instruments do you use in your practice?

Have you considered different machines?

How much down time do you have with the machines you use?

Do you know how many tests are repeated as the machine did not give results, or they were physiologically impossible?

Clinical pathologists have a fondness for instruments, and most can troubleshoot and repair the machines

Laboratory technologist are also trained on machine maintenance and can assist with the troubleshooting and maintenance of the machines.

You can get this equipment and you can get it at reasonable prices, you just need to know where to look and what equipment will work in your situation.

The major suppliers that I am familiar with are:

Hematology: What is important here is minimum volume

and speed of the assay.

ABBOTT – CellDyn 3700 SEIMANS – Advia 120

Chemistry:

Roche – Cobas

Seimens – Dimension

Olympus – Olympus au400

Endocrinology:

Seimens: Immulite

Beckman

You need speed and volume control with these instruments but also open channels so you can program veterinary specific tests.
You can deal directly with the manufacturers for refurbished equipment or you can deal with companies that provide second hand machines.

Machines

If you get from the refurbished dealers:

You do need to have the machines checked by the manufacturer if you wish to maintain a maintenance contract on these machines.

They need to certify them as FDA approved or they will not honor maintenance contracts, however you can still get them to work on the machines.

Dependent on the area you will also find instrument service organizations that can service your instruments although they are not the manufacturer's service reps.

For example: we use Minnesota Medical to service the CellDyns and they fly out once/year and are available by phone on a daily basis.

It is a good idea to check with the hospitals in your area determine what machines are being used there, as the availability of help is greater if the particular brand is the common one in the human hospitals.

Second hand instrument dealers include:

DiamondDiagostics

Myco Instrumentation

Block Scientific

You can also get instrumentation from E-bay – especially the smaller equipment items. Miscellaneous equipment would include centrifuges, incubators, heat blocks, slide stainers, rotators etc.

	COST	MAINTENANCE/year
Hematology analyzer CellDyn 3500	$8000	$3000
Chemistry analyzer – Dimension with water system	$39,000	$13,500
Immulite 1000	$9000	$6000
Nova blood gas	$4500	$900
MISCELLANEOUS LAB EQUIPMENT as detailed above	$15,500	$1000
TOTAL COSTS	$76,000	$24,400

QUALITY ASSURANCE PROGRAMS

This includes all aspects of QA – and is applied to every aspect of the laboratory which includes

-preanalytical

-analytical

-post analytical

Basically this deals with

Training of personnel; both laboratory and those collecting samples.

Development of SOP's for all aspects of the lab.

Establishment of methods to deal with non-conformances.

Establishment of test methods, reference intervals, interferences.

Review of final results, providing interpretations of these results.

How many of you do statistical QC on your instruments? How many have a manual to outline non-conformances and how to deal with them?

DRUGS

o Many drugs cause both idiosyncratic as well as predictable reactions.

o Some of these are actual abnormalities (physiologic) whereas others are direct interferences with the test.

Examples: methimazole will decrease ALT

Metranidazole will increase.

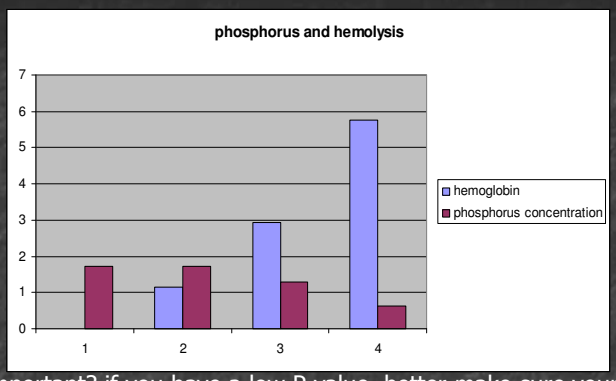
Ursodial can cause significant increases in GGT

Cephalosporins will cause increased ALT/AST

Anesthesia marginates WBC, Neutrophils, and will also cause a decline in PCV, TP, Albumin

PRACTICAL APPLICATIONS OF VESSEL STASIS

	Values	Reference	REDRAW
BUN	42	14-35	31
Creatinine	1.9	0.9-2.05	1.3
Sodium	158	143-155	151
Potassium	3.1	3.6 -5.6	3.7
ALT	153	34-110	92
PCV	47	31-49	41
WBC	3.8	4.0-16.0	7.2



Important? if you have a low P value, better make sure your sample was not hemolyzed.

Basically, hemolysis can decrease P levels to zero decrease creatinine, increase TP/ALB, Lipemia can decrease calcium, increase albumin, and icterus will decrease Creatinine, lipase.

Interferograms are instrument/methodology specific

4 yr old S/F Collie X with history of progressive wt loss, variable activity level. Current on vaccinations, temperature 40C; modestly increased heart rate.

Total Protein	8.6	5.4 – 7.1 g/l
Albumin	5.2	3.1 – 4.2 g/l
Calcium	17.6	9.0-11.5 mg/dl
Creatinine	0.5	0.6-1.8 mg/dl
Total Bili	1.2	0- 0.6 mg/dl

First sample was very hemolyzed with slight lipemia.

Actual Values
Total Protein 8.1
Albumin 2.2

Calcium 9.0

Total Bili 0.2

Creatinine 1.5

Biological variations:

Age:

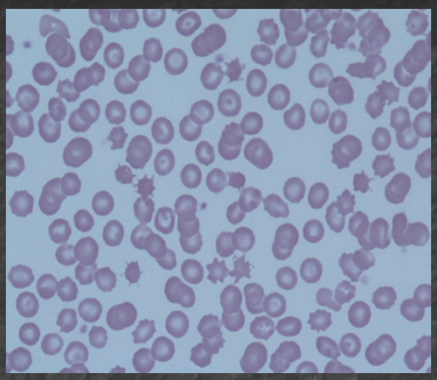
This is one variable that has been explored in animals: These are reference intervals for felines

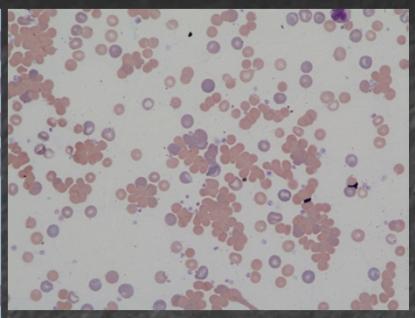
Values:	Reference	Correct reference
BUN 37	15.0 – 35.0	14.0 – 39.0
Creatinine 1.5	0.9 – 2.04	0.8 – 1.5
Calcium 11.2	9.0-11.0	9.6 – 11.6
Phosphorus 9.4	3.5 - 6.0	5.7 – 10.2
ALP 173	0 – 58	40 – 195
Urine SG 1.018	>1.035	1.008 – 1.035

Hematology				Comparative hem-Schalm
wbc	x10-3	2.9-19.4	4.0-16.0	5.5-19.5
polys		2600-10200	2700-10500	2,500-17,500
bands				0-300
lymphs		1100-7500	1170-6600	1500-7000
monos		0-900	0-870	0-850
eos		0-2050	0-1250	0-1500
baso		0-200	0-100	rare
rbc	x10-6	4.5-10.0	6.3-10.8	5.0-10.0
hgb	g/dl	8.0-14.5	10.2-16.1	8.0-15.0
hct	%	25-44	31-49	24.0-45.0
mcv	fl.	34-48	41-55	39-55
mch	pg	12.0-16.0	13.0-17.0	12.5-17.5
mchc	g/dl	31-36	30-36.0	30-36
rdw		11.0-26	10.0-26	
plt count	x10-3	300-800	300-800	

Feline age related reference intervals for cats – compared to historical

CYTOLOGY AND HEMATOLOGY





The correct interpretation of these smears can lead to a rapid diagnosis.

CYTOLOGY

How often are you using PARR tests to confirm lymphoma?

You could use cytology slides in house to determine T and B cells

You can also expand cytology to include:

-cytochemistry for leukemias

-ALP for bone tumors

-cytokeratins, vimentin and desmin, VWf

-acid fast stains

-fungal stains

-copper stains

-histiocytic markers, CD11,CD18, E-cadherin

-Melan A or S-100

These could all be developed in house, and will cut time as well as ensure diagnosis prior to surgery.

Manuals developed for QA

Manuals

-Dimension expand training manual

-Hematology and Celldyn manual

-Cytology manual

-Laboratory accession manual

-Miscellaneous test procedure manual

-Blood banking manual

-Immulite manual

-QA assurance manual

Format is standard

-Name of test

-Methodology

-Significance

-Technical information –calibrations

-Procedure

-Procedural notes(sample amt, type, critical levels).

-References

Analyte	Calibration time	Calibrator	Upper limits	Technical notes	Control
ALP	90 days or new lot	Liquid -3 levels	1200 IU/L	Enzyme errors	Multiqual 1,2,3
BUN	30days or new lot	Dry, prepare with DH20 3 levels	175 mg/dl	Dilute only 1:3 check P levels	Multiqual 1,2,3
KBromide	30 days	1 std, dilute 1:2 of level 2, distilled H2O for 1	3.0	If hemolyzed, use special procedure	2 levels, low and high
Lytes – Na, Cl, K	7-10 days	Automatic every 2 hrs	Na>200 K>12 Cl>200	Low limits Na<75 K< 1.0 Cl <65 DO NOT DILUTE	Multiqual 1,2,3
Lipase	60 days	Std dilute in DH2O	>2500	Zero values absorbance	Multiqual 1,2,3

Check Lists and other training materials

- Training schedules
- Basic lab checklist
- Technician checklist
- CellDyn checklist
- Nova Check list
- Dimension Check list
- Lab orientation check list
- Immulite check list
- Hematology training
- Fecal evaluation
- Urinalysis
- Cross march

LOOKS LIKE THIS WILL TAKE A LOT OF TIME AND EFFORT!!!!

HOW DO YOU DO THIS AND NOT LOSE MONEY?

Power point and interactive methods are used for the last 4; hands on training is required for the checklists.

COST OF TESTS

TEST	CONSUMABLE COST – REAGENTS AND MAINTENANCE	COST OF OVERHEAD, PRODUCTION EXPENSE, TECHNICAL WAGES, PATHOLOGIST	AVERAGE TOTAL NUMBER OF SAMPLES/MON	REVENUE – consumables and reagents	PROFIT – COMMIISSIONS 25%
Basic chem. Panel	2.53	$27.85	100	8000 – 3038.00 = 4962	4962-2000 =2962
CBC with manual diff	1.89	$19.06	156	7800 – 3268 =4532	4532-1950 = 2582
Combined Panel with CBC/diff and chemistry	4.42	32.50	203	26390 – 7494.75 = 18895.25	18895.25 – 6597.5 = 12298.

Revenue is figured on $50.00 for CBC, $ 80.00 for chemistry and combined panel is $130.00. Profit generated = $17,800

In the example:

Chemistry includes Glucose, BUN, Creatinine, Na, K, Cl, Ca, P, TP, albumin, Tbili, ALP,GGT ALT, AST, CK and cholesterol.

The work is done for the most part by MLT's or personnel with BSc degrees. There are 2.5 lab technical employees. They staff the lab 8-10hours/day with overlap so Monday through Friday the lab is open from 8 am – 6 pm. (hours are longer as the techs come in before lab is open in order to check the instruments and start QC). After hour procedures are run by emergency personnel who are trained to run these instruments.

The samples run at night are approximately 6% of the total samples run in the lab.

The profit ($17,800)with these figures for these 3 tests generated in the lab at the same time these machines are under maintenance contracts and maintained to FDA standards with 3 levels of controls run daily and a pathologist on site.

What is your profit on lab tests? What is the cost of reagents for your instrumentation?

This data does not include all tests, and specifically excludes bile acids, phenobarb, nova tests, coagulation, in house cultures, serologic tests, and all sendout tests.

tests	chem	Chem./cbc	exp	geri	Presur	lytes	Cbc	Pcv/pp	ua	fecal	xmatch	singles	cyto
Number	140	241	8	87	33	40	136	150	108	10	23	156	89
charges	14420	37355	1376	16791	2739	1640	5800	5700	4536	360	3200	4028	8099

The figures used to calculate revenue were averaged. The % cost of consumables which includes all consumables not just reagents is $7650.00 which is 7.4% of revenue.

The revenue on average for this test distribution would be $103011.00

The commission cost at 25% is $25752.75; while assuming all other costs of overhead and salaries at 35% of the total revenue would equal $36053.85. The total net profit at these figures would be 103011-25752.75-36053.85-7650= $33554.4 or 32.5%

It is important to note that not all lab tests have the same profit ratios. You may also have higher overhead costs but even at 40% the profit generated would be $28,000 or 27%

COMPARISON TO ANOTHER REFERENCE QUALITY LAB WITHOUT THE SPECIALISTS

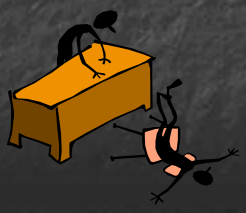
tests	chem	Chem. /cbc	exp	geri	presur	lytes	cbc	Pcv/pp	ua	fecal	Eq/la	Immul	Cytos
Number	32	91	74	86	27	33	101	233	118	272	65	153	49
charges	2624	12376	11248	14276	1728	1468.5	5252	4893	6136	7272	6500	8415	2450

For this practice the mix of tests is different and the charges are less than at the specialty practice.

The total revenue would be $ 84638.5, the commission would be $21159, comsumables were $6100.00 and the overhead is @ 35% =29623

Cost of the tests is 84638.5-21159-6100-29623 = 27756.5 or 32.7%

So the 2 practices are receiving the same benefits.



REFERENCE LAB CHARGES

-Averages for our area

-Cytology	single site $40.00
-CBC with diff	$22.50
-General Panel –CBC/chem	$42.00

Average charges for these tests to clients are 2.5 to 3x the price so that would be

Cytology	$100-120.00
CBC/diff	$56- 67.5
General panel	$105 - $126.00 (LOWER CHARGE –DIFFERENT TESTS)

What you need is to try and keep your costs in line with what the reference labs are charging you, bearing in mind that their charges also include courier pickups.

WHAT IS THE PROFIT MARGIN FOR THE REFERENCE LABS

-IN GENERAL THIS RUNS 35-38%

Why don't you just use the reference labs?

- Results are delayed and depend on the number of pickups and the location of the reference lab
- Can you be assured of Quality with these labs? Again there are no rules or regulations that govern these labs.
- Can you make more profit with the in house tests?
- Will in house testing provide you with a better chance at diagnosis and treatment, if so how?

OTHER REASONS?

You can customize the tests you run; set your own panels that fit better with your practice situation.

What can you do in an in house reference quality lab:

o There is always an issue with referrals as the referring clinics like to do their own blood work and likely do not consider your testing to be superior to theirs. If you can demonstrate that your results are more accurate, precise and your reference intervals are specific to your area, you could generate more revenue.

o As a specialty hospital you could be on the forefront of testing procedures and be able to do special tests in house including Serum amyloid A and C-reactive protein (big tests in Europe)

o Better drug testing especially in those states that now have legalized Marijuana

o Specific coagulation testing, not just the point-of care tests- you could do Protein C in house.

o Gross necropsy – clinical pathology programs do include gross pathology, and some pathologists are more interested than others but these will help your morbidity and mortality rounds. Most resident programs require a clinical pathology rotation.

REFERENCE QUALITY LAB CONT'D

- ❑ Increased use of tests such as Cardiac troponin, ACTH
- ❑ Reference interval development that is breed, age as well as species specific and fits your population demographics. The diagnosis of "disease" vs "health" in laboratory diagnosis rests entirely on the accuracy of your reference intervals.
- ❑ Interaction with a clinical pathologist will aid in establishing "critical decision levels" as these should reflect the methods used, the variability of the method, the interference factors and the effects of the diagnosis.
- ❑ Immediate access to a cytologist/hematologist who can discuss the results with you in "real time".
- ❑ If your practice is large enough you could also consider hiring an anatomic pathologist (Angell Memorial has a path department) and then include histology slide preparation in house. This will cut down on time, and increase accuracy as the pathologist will trim the tissue and follow the tissue through the processing as in human medicine. But profits for histology are lower than for other aspects of the lab.

THE END

Any questions ?