

ZRT LABORATORY DOSAGE AND RANGES

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Hormone supplementation should not be changed based solely on patient's laboratory levels.

Ranges & Dosage Table of Contents

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CLINICIAN GUIDELINES

How to read the graphs:

The charts graph the dosages of the hormones on the horizontal (x axis) and the lab values ZRT has observed on the vertical (Y axis).

The lines represent the 80/20 cutoffs – 80 percent of the people will be below the top line (red) and only 20 percent of the people will be below the bottom (blue) line. Thus between the red and the blue line you can see the lab values of 60% of all people tested. The purple line in the middle represents the median, where the majority of people's lab values fall.

All data is for 12 hours and/or 24 hours after supplementation. Your patient's lab results may be higher or lower if they tested less than, or greater than, these timeframes.

To determine your patient's position on their supplementation type graph: determine their dosage and their lab values on the corresponding x and y axis. Where these lines intersect is where their level would be.

Graphs are provided on their own individual pages so that you may print them out, laminate as needed, and/or provide them as teaching tools for your patients.

Remember that this is a tool. Lab values are influenced by the supplementation dosage, the base cream or gel, the absorptive quality of the supplement, the absorptive quality of the patient's system, the metabolism of the hormone for that patient, and the amount of time since the patient last supplemented. Some patients will have lower lab values than expected with excellent symptom control and others may have higher lab values for their dosage with poor symptom control.

If you have questions about symptoms and labs please call the ZRT clinical consultants at 1-866-600-1636. They are available 8AM -5PM; M-F Pacific Time; without an appointment.

F.A.Q.

How did ZRT get this data?

ZRT has an extensive system database of lab values for both men and women along with their hormone supplementation. This database is now greater than 1 million individuals. When individuals test they are asked for: their age, menstrual status, supplementation type and method, dosage, timing of last dosage, duration of supplementation, and symptoms. All of this information is added to our extensive database for the purpose of continuing to evaluate our ranges and to provide added clinical guidance for healthcare providers in practice.

Is this information published? Some of this information has been published and has been presented in abstracts and poster studies. We hope that we will be able to publish more extensively in the future. Please do not use this information in publications without contacting ZRT for approval. These images are copyrighted. These graphs can not be used to correlate labs tested at another lab facility.

Why are levels different if everyone is taking the same dosage? Your patient's laboratory levels are dependent on their dosage, the base of the cream or gel, how well their skin absorbs the creams, and how quickly the liver processes the hormones. Constipation or bowel frequency and thyroid disease may also make significant changes to a patient's lab results. Some people may have high values with small dosages and vice versa.

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My patient's labs are outside of the lines what do I need to do? Remember that this is a tool and does not replace your professional clinical experience. Some people may not have symptom relief until levels are higher than the top line or may have symptoms of too much hormone if levels are above the bottom line.

My patient's lab value is above the top line; what do I do? Your patient's level is higher than 80% of people taking the same dosage. If the value is above the top line, it means that your patient produces higher lab levels for the same supplementation dosage as compared with other people. Your patient may be taking a higher dosage than prescribed or may have not waited 12 hours between supplementation and testing. Constipation, medications, kidney or liver disease, and/or hypothyroid individuals may not metabolize the hormones as quickly or as well as other patients, resulting in higher lab values.

My patient's lab value is below the bottom line; do I need to increase their dosage? Remember that this is a guideline. Your patient's lab value is less than 80% of people taking that same dosage; less than 20% of people will be in this category. This might mean that your patient: may be using a smaller dosage than prescribed, may not absorb 100% of your product, may have stopped hormones greater than 24 hours prior to testing, and/or may metabolize hormones faster. Individuals using certain medications that up-regulate P450 liver enzymes or those that are hyperthyroid may metabolize their hormones faster. You may also need to look at a different graph if they used their hormones greater than 24 hours.

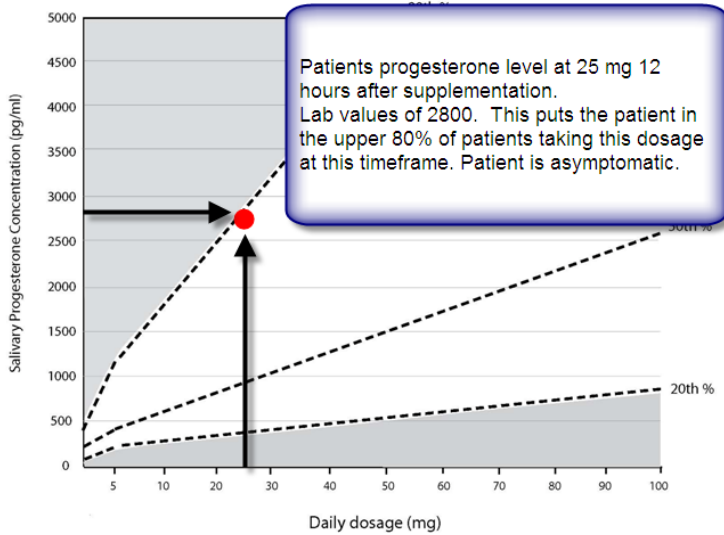
My patient's hormone supplementation type doesn't have a graph? Graphs have not been provided for hormone supplementation where they are not helpful clinically or ZRT does not have sufficient data. It does not mean that you should change your patient's hormone supplementation.

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EXAMPLES

Salivary Progesterone -
12 hours After Topical Supplementation

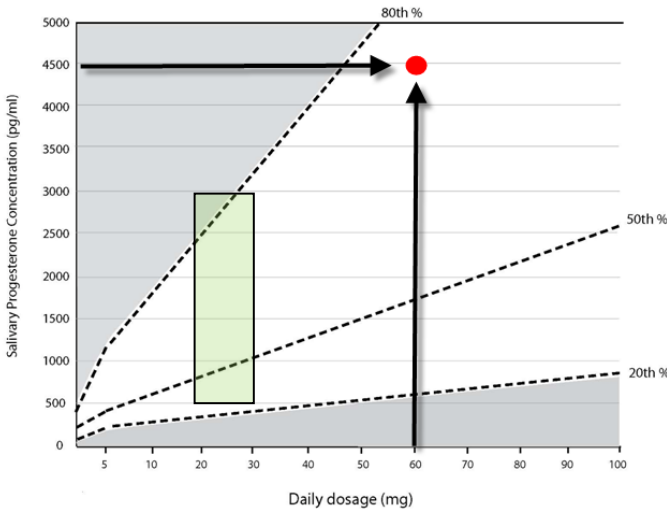


Example 1: Patient using standard dosage

Determine the patient’s dosage on the X axis (25mg in this case) and following vertically, find the patient’s lab results on the y axis – in this case 2800. In this example, the patient is in the upper 80th percentile of patients taking the same dosage.

Hint: remember the top of the white band and the bottom of the white band represent the 80% and 20% lab values for increasingly higher dosage of topical progesterone used 12 hours prior to testing.

Salivary Progesterone -
12 hours After Topical Supplementation



Example 2: Patient using higher dosage

ZRT sets a lab range of 500-3000 for individuals using 20-30mg of topical progesterone (see green box). In this example, the patient’s progesterone dosage was 60mg, outside of the dosage that ZRT used to establish the supplementation range. This patient’s lab result was 4500. As a result, this patient’s lab result was flagged as high on ZRT’s results. However, the lab result is within the range expected based on this higher dosage. Because the patient was clinically doing well on this dosage and had not done well on lower dosages, the patient maintained their dosage.

SALIVA: NON-SUPPLEMENTING RANGES

Women			
Estradiol	Premenopausal	Follicular	0.5-1.7
		Luteal	1.3-3.3
	Postmenopausal		0.5-1.7
Progesterone	Premenopausal	Follicular	12-100
		Luteal	75-270
	Postmenopausal		12-100
Testosterone	Age dependant		16-55
Estrone			1.6-5
Estriol			Less than 7
MEN			
Estradiol			0.8-2.2
Progesterone			15-100
Testosterone	Age dependant		44-148
BOTH SEXES			
DHEAS	Age dependant		2-23
Cortisol	Morning		3.7-9.5
	Noon		1.2-3
	Evening		0.6-1.9
	Night		0.4-1

ESTRADIOL SUPPLEMENTATION CHARTS

BiEst – Estriol and Estradiol. Commonly compounded, this product is not available through retail pharmacies. This formula has now generally replaced the TriEst formula for most practitioners. BiEst is used topically, orally and vaginally. Formulas may have different percentages of estriol and estradiol. Common formulas contain 50/50 (1:1) which is 50% of Estriol and 50% Estradiol or 80/20 (4:1) containing 80% Estriol and 20% Estradiol. Estriol is always reported first in the ratio of BiEst in the classical format. The overall dosage of BiEst is reported. A standard prescription may be written as topical BiEst 50/50 1.0mg/1ml use 1ml daily. Since topical BiEst is the most common, that graph is provided.

Estriol – Many women use estriol vaginally which does not change estradiol levels. Oral supplementation of estriol produces ranges of 5-20 pg/ml and topical supplementation produces ranges of 5-100 pg/ml. However, due to the low number of women using estriol only supplementation, ZRT did not generate these graphs.

Oral Contraceptives – 0.5-2.2pg/ml. Oral contraceptives are of two varieties – ethinyl-estradiol and a progestin or a progestin only. Progestin-only contraceptives generally do not change the estradiol lab results. Ethinyl-estradiol is not structurally identical to estradiol and contributes to suppression of ovarian function. Because it is not bio-identical, ethinyl-estradiol levels can not be measured in ZRT's laboratory testing. Therefore, laboratory findings of estradiol in women using oral contraceptives are generally expected to be suppressed. However, ethinyl estradiol has a high estrogenic effect on tissues and causes an increase in liver binding proteins. Patients may have symptoms of estrogen dominance because of the estrogenic effect. Because laboratory findings are unremarkable and suppressed, ZRT has not provided graphs for this hormone supplementation form.

Oral Estradiol – Available through standard retail as well as compounded pharmacies. This graph does not include women who report using a formula of BiEst (Estriol + Estradiol). Brand names include: Estrace™.

Pellet Estradiol – Available through compounding only, estradiol pellets are inserted under the skin to slowly dissolve over a period of 4-6 months. Levels are very sustained and even. Because of this graphing is not provided.

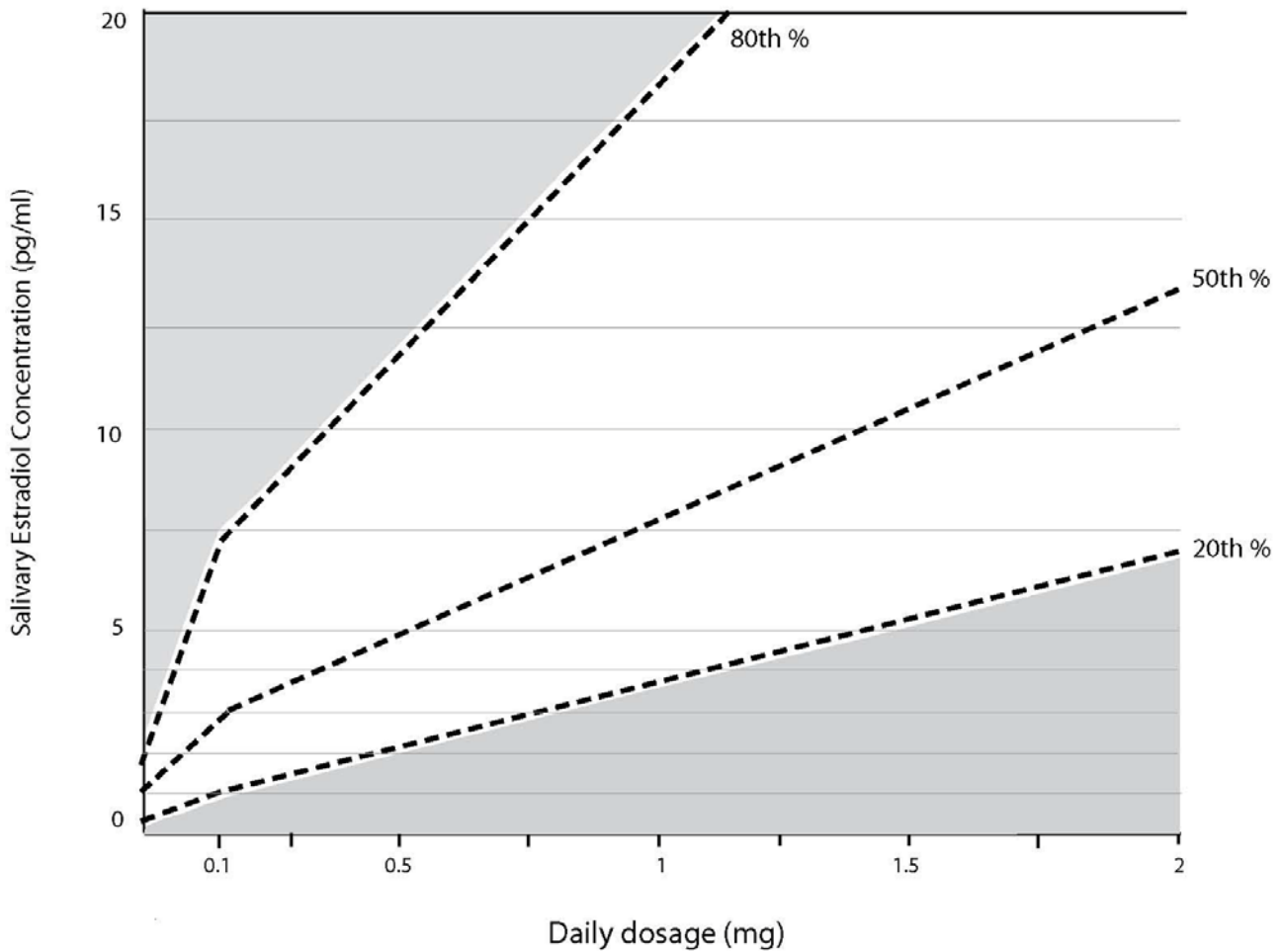
Topical Estradiol – Available through standard retail as well as compounded pharmacies. This graph does not include women who report using a formula of BiEst (Estriol + Estradiol). Brand names include: Divigel™, Estrasorb™, EvaMist™, Elestrin™, Estrogel™.

Transdermal Estradiol Patches – Transdermal estradiol patches are bio-identical estradiol provided in a patch. This is one of the lowest and most even delivery system of all hormone supplementation methods. Because of this, lab values are so consistent as to be unremarkable in graphing. Brand names include: Vivelle™, Climara™, Estraderm™, Esclim™, Alora™, Menostar™.

Triest – Estriol, Estradiol, and Estrone – While common in the past, the last 10 years has seen triest fall out of favor due to the estrone content. As a result, ZRT does not have enough data points to generate clinically and statistically significant information.

Oral Estradiol, 12 hours

Salivary Estradiol (E2) - 12 hours After Oral E2 Supplementation



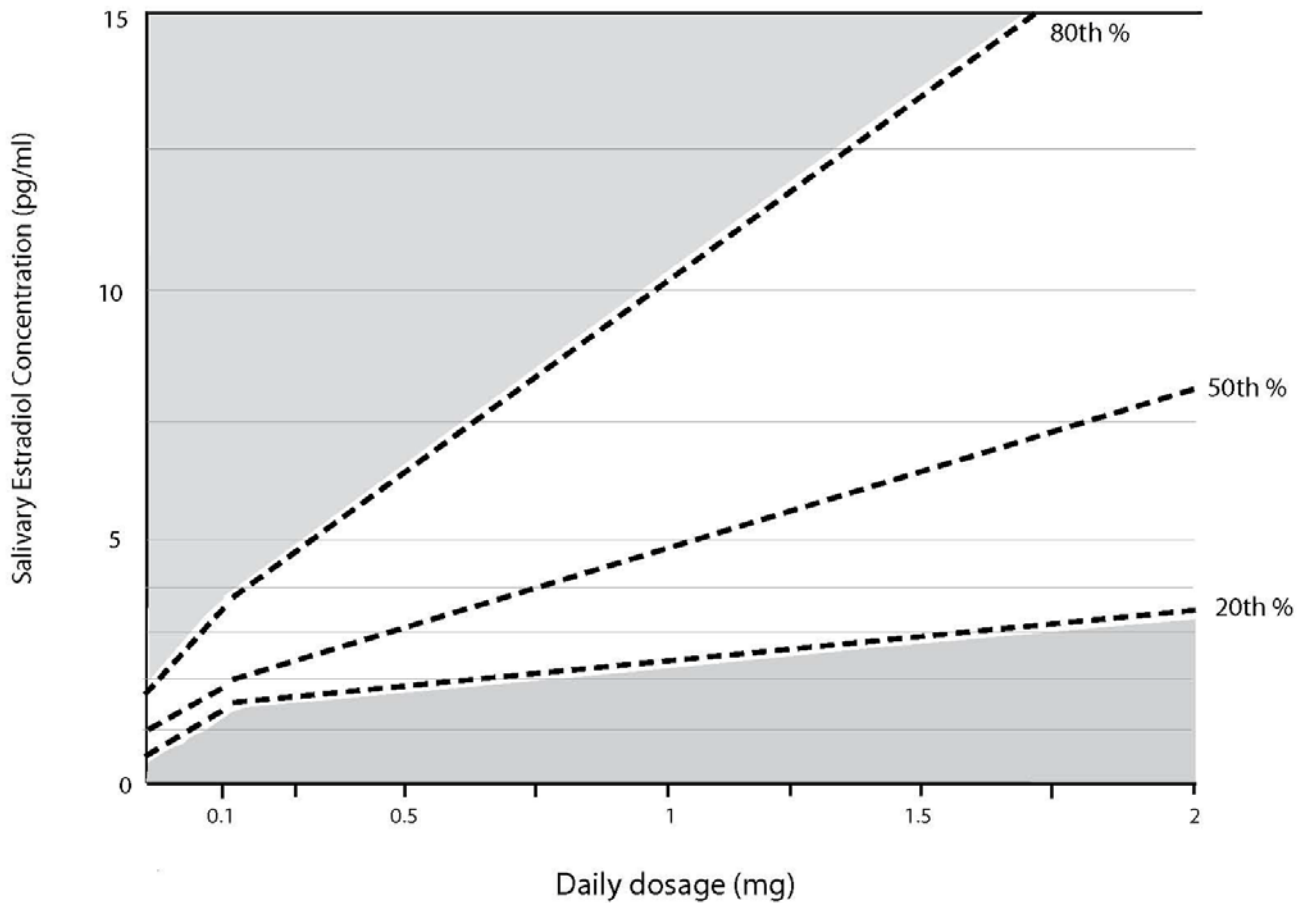
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Oral Estradiol, 24 hours

Salivary Estradiol (E2) - 24 hours After Oral E2 Supplementation



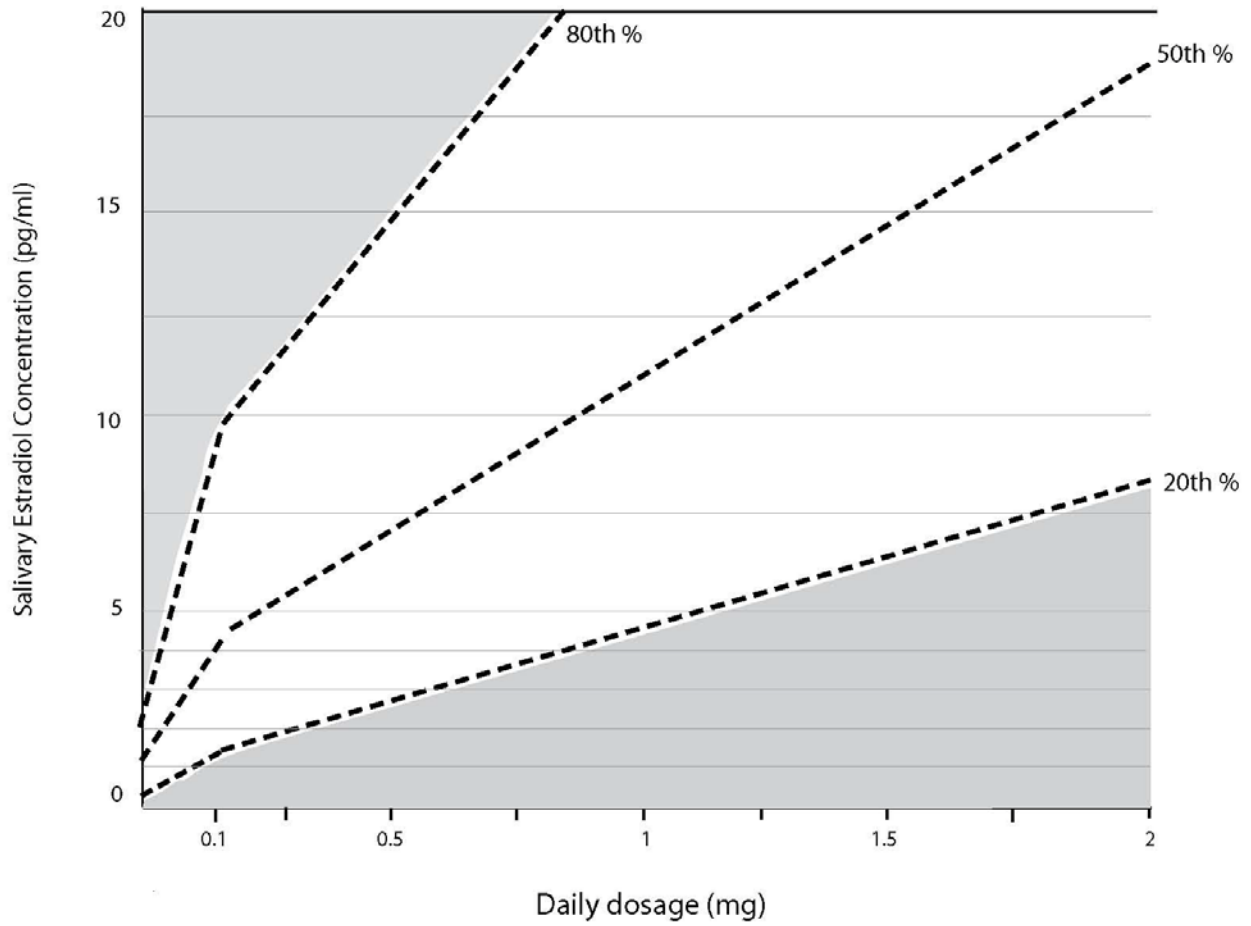
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Topical Estradiol, 12 hours

Salivary Estradiol (E2) - 12 hours After Topical E2 Supplementation

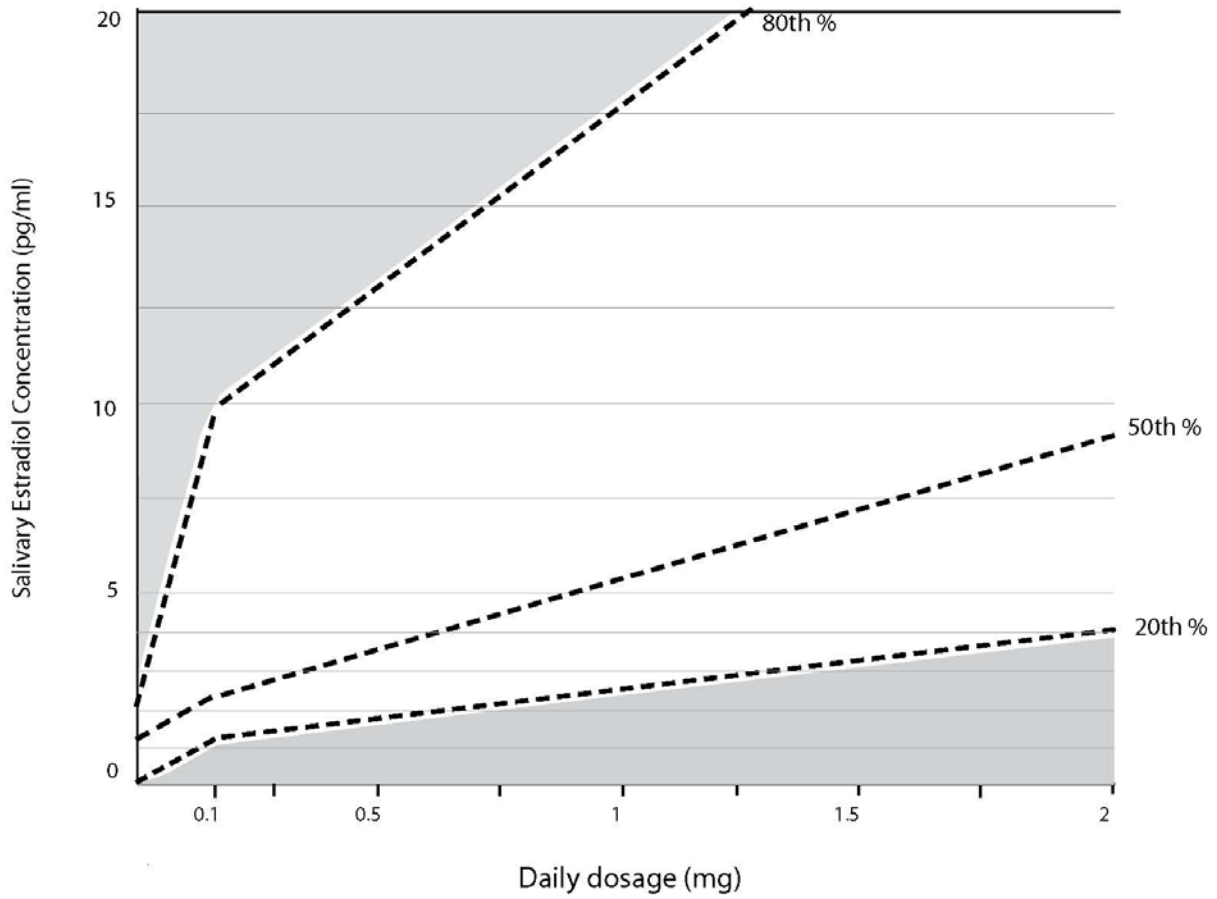


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Topical Estradiol, 24 hours

Salivary Estradiol (E2) - 24 hours After Topical E2 Supplementation



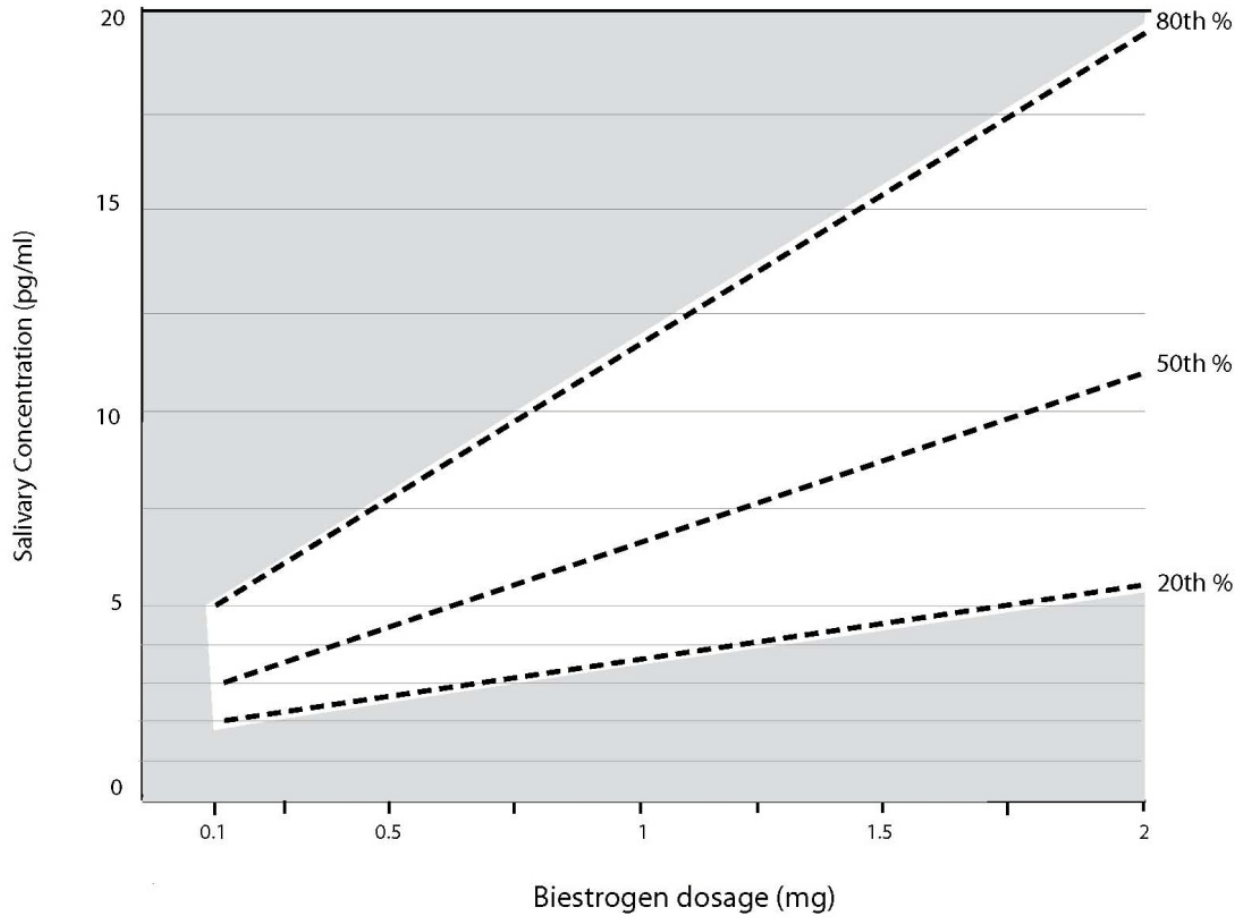
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Topical BiEst 1:1 (50/50), 12 hours

Topical Biest 1:1 - 12 hours After Supplementation



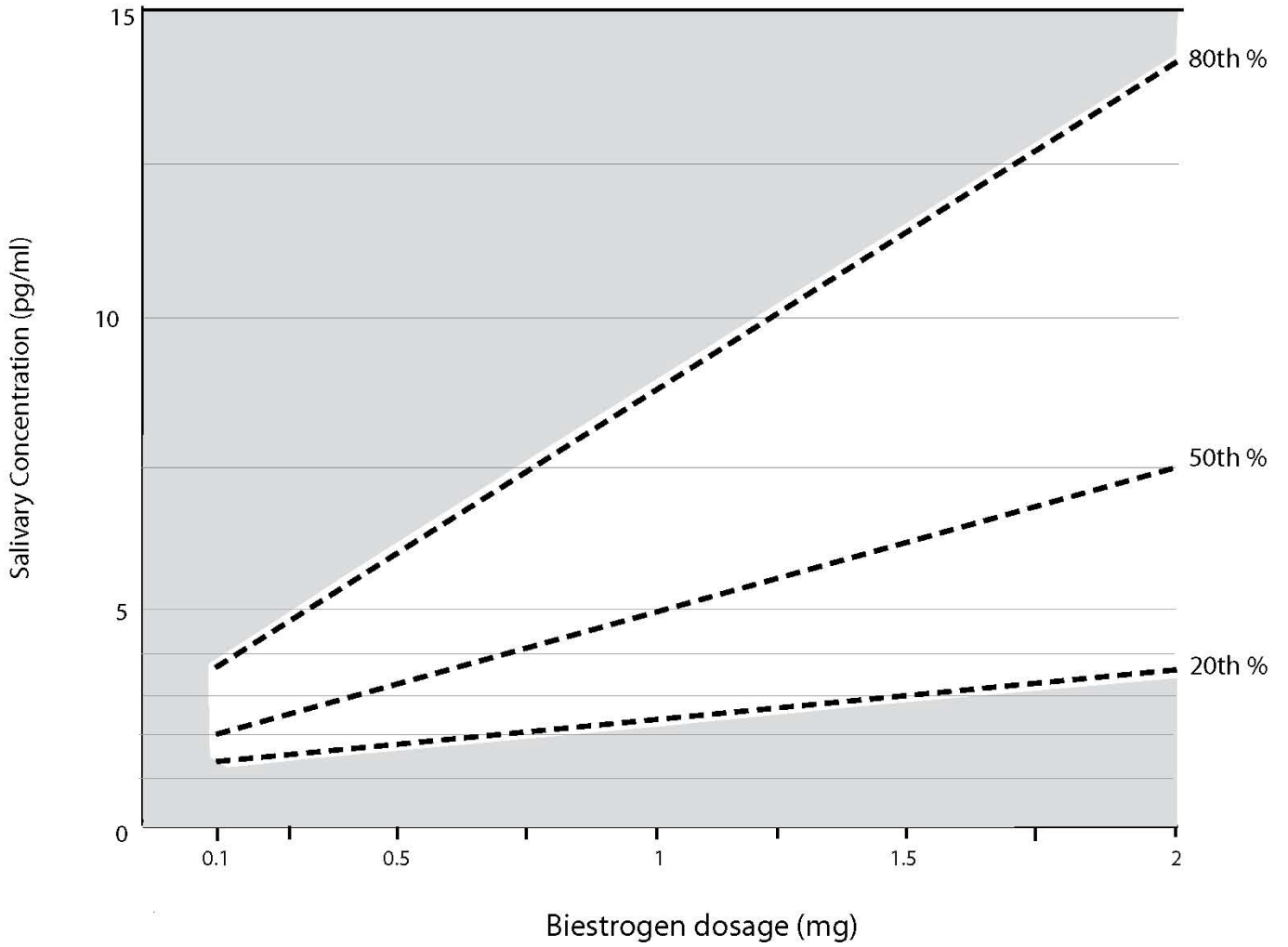
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Topical BiEst 1:1 (50/50), 24 hours

Topical Biest 1:1 -
24 hours After Supplementation



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PROGESTERONE SUPPLEMENTATION

Injectable Progesterone – Range 75-270. Injectable progesterone is rarely seen at this time in supplementing patients. Therefore ZRT does not have the numbers to offer graphs that are clinically or statistically significant.

Oral Progesterone – Range 30-300 pg/ml. Oral progesterone is poorly absorbed and very quickly metabolized. Studies show that peak serum levels are found 3 hours after supplementation. Brands include: Prometrium™. 12 Hours after supplementation salivary levels are not expected to remain elevated.

Progestin supplementation – Range 10-53 pg/ml. Progestin-only contraceptives as well as other progestin supplementation causes suppression of endogenous progesterone production. As a result, ZRT sets ranges that are generally consistent with a non-ovulating woman. While progesterone levels are suppressed, body tissues may be exposed to high levels of progestins. Progestins will generally act on the uterus similarly to progesterone, but are known to have separate actions in the blood vessels and veins and adverse reactions as compared with progesterone. Graphs are not provided since results are consistently low and clinically not relevant.

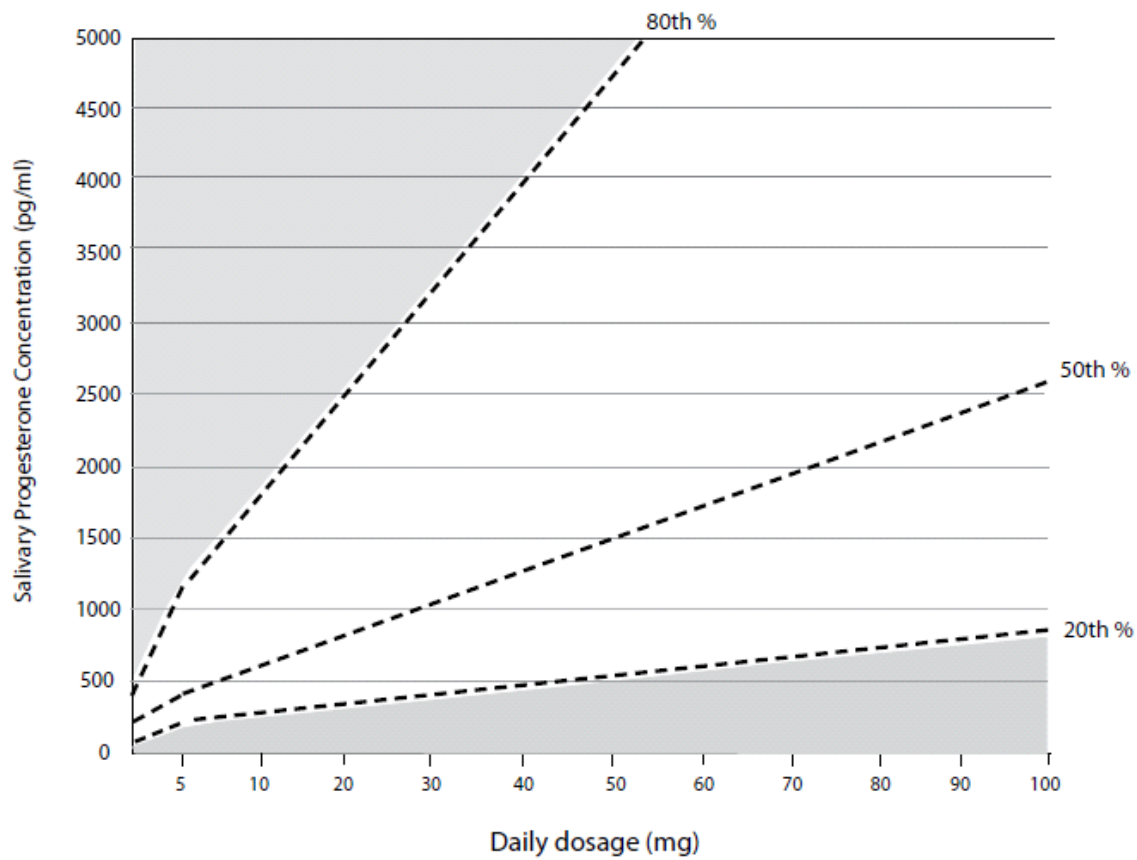
Sublingual Progesterone – Troche and sublingual progesterone is not as common a delivery method as oral or topical progesterone. Due to contamination issues, ZRT recommends testing individuals using sublingual progesterone in capillary blood spot.

Topical Progesterone – Available over-the-counter (OTC) or compounded. OTC progesterone generally is manufactured to provide 20-25mg of progesterone per dosage. Compounded progesterone may be created at lower and much higher dosages. Therefore, compounded products and OTC progesterone differ by their dosage of progesterone and the formulation of the base creams or gels. However, if using 20-30mg of progesterone daily, both forms are expected to produce the same lab values. Use the charts below for appropriate ranges for a given scenario.

Vaginal Progesterone – Range 200-3000. Vaginal progesterone is well absorbed. It may be given at dosages commonly seen in topical and sublingual progesterone. Sometimes progesterone may be given at much higher levels for pregnancy maintenance and lab levels and dosages may no longer be found on the chart. Although, ZRT tests many women who are using vaginal progesterone, this is a rare mode of supplementation and ZRT does not have a statistically significant patient numbers. Brands include: Crinone™, Endometrin™, Prochieve™.

Topical Progesterone, 12 hours

Salivary Progesterone - 12 hours After Topical Supplementation



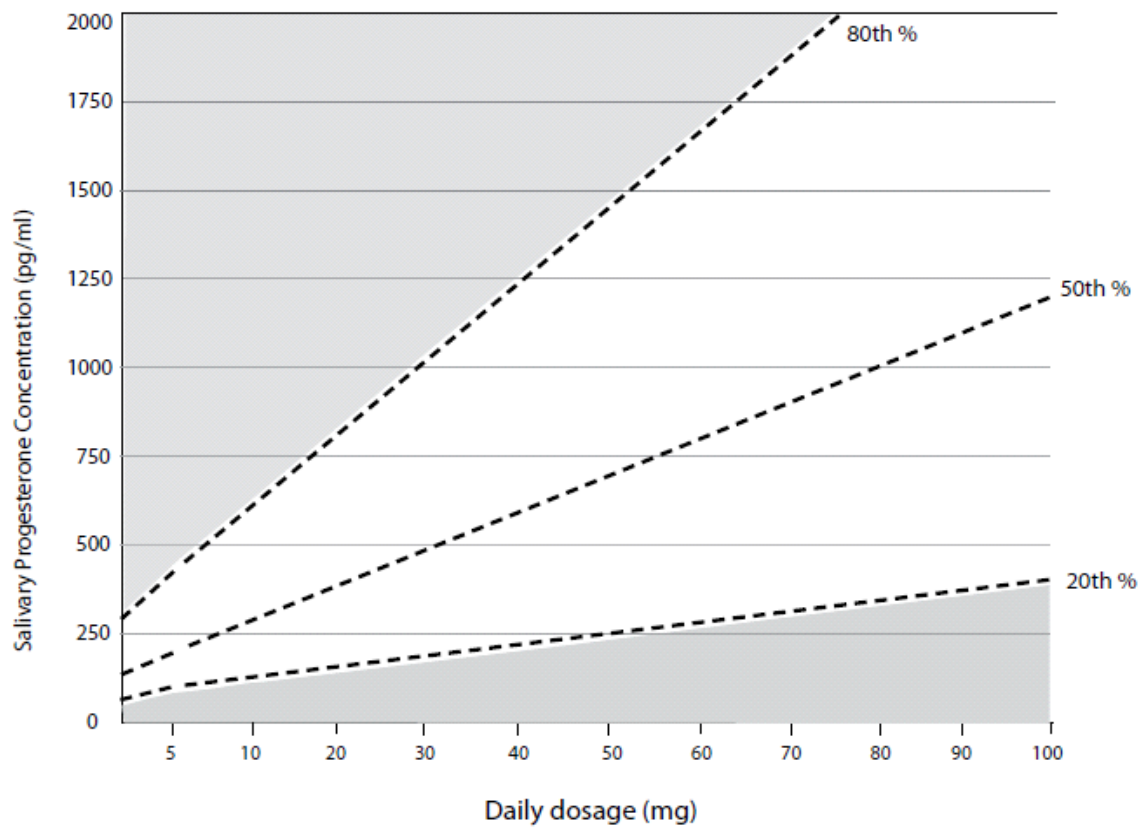
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Topical Progesterone, 24 hours

Salivary Progesterone -
24 hours After Topical Supplementation



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TESTOSTERONE SUPPLEMENTATION

Injectable Testosterone – Physiologic ranges for men and women. Because individuals generally do a once monthly testosterone injection, but may collect anywhere from 2-3 days after supplementation to the day before their next injection, the graph of this information did not provide clinical utility on dosage.

Oral Testosterone – Physiological ranges for men and women. Oral testosterone is poorly absorbed and up to 44% is cleared by first pass metabolism of the liver. Because of this, few individuals use oral supplementation.

Pellet Testosterone – Physiological ranges for men and women. This form of testosterone tends to produce very consistent and even dosage delivery. ZRT does not yet have the numbers to provide clinical or statistical significance.

Patch Testosterone – Men range 115-800; not available for women. Patch testosterone tends to produce very consistent and even dosage delivery. Because of this, the graph is not clinically relevant at this time. There is no testosterone patch for women available at this time.

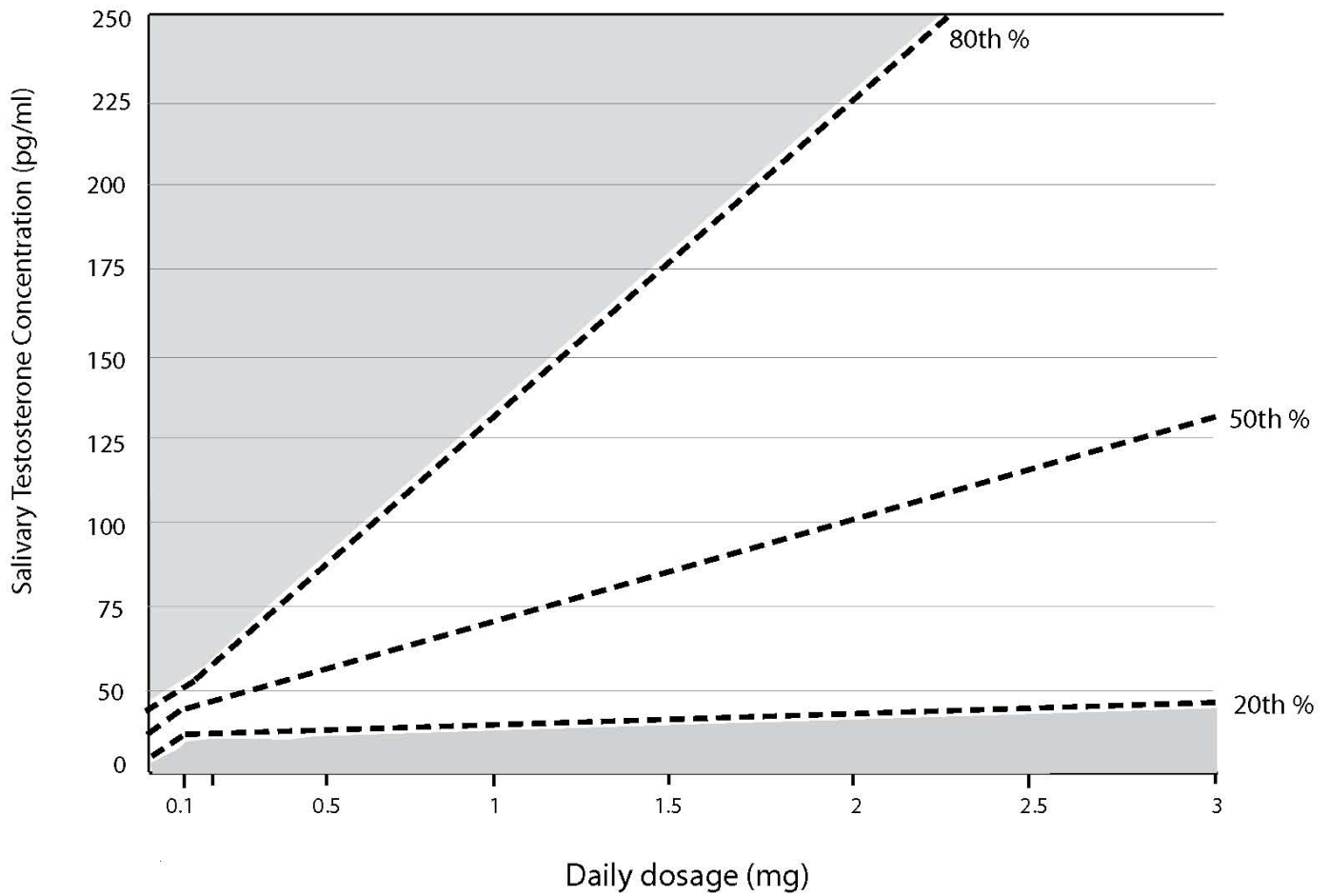
Sublingual/Troche Testosterone – Because saliva tests may be contaminated due to patient collection, the graph is not clinically relevant at this time. Due to contamination issues, dried blood spot is the preferred method of testing.

Topical Testosterone – Men- see graphs below; physiological levels for women at 24 hours post supplementation. Men and women use dramatically different dosages to achieve hormonal balance. Because women fall within the physiological range within 24 hours, only 12 hour topical supplementation is reported below in graphical form.

Vaginal Testosterone – Men not available; physiological ranges for women. Vaginal testosterone may be very effective for both systemic effects and localized vaginal effects. However, at this time, ZRT does not have the numbers of women supplementing and testing this way to provide clinical or statistical significance.

Female - Topical Testosterone, 12 hours

Salivary Testosterone, Female - 12 hours After Topical Supplementation



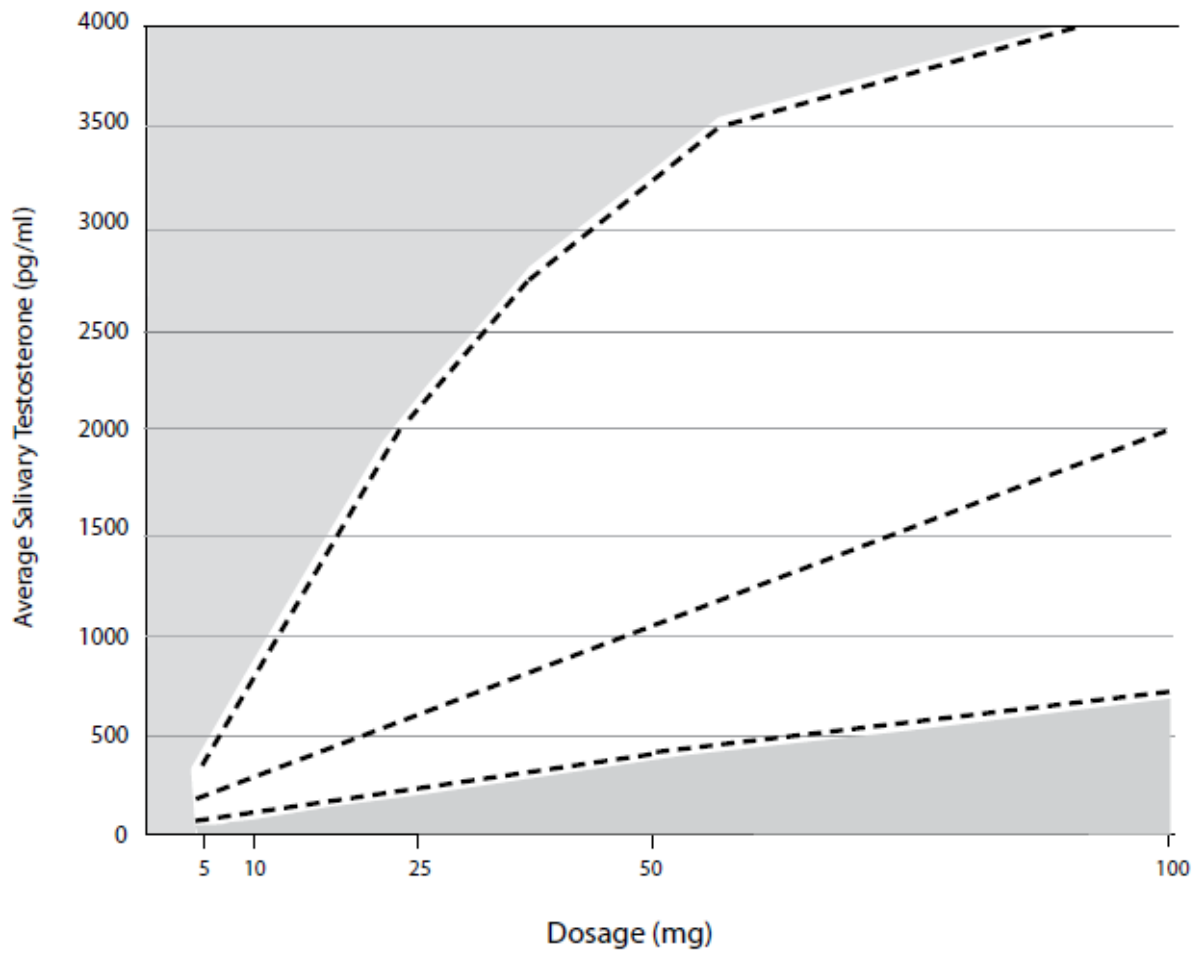
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Male - Topical Testosterone, 12 hours, 100mg dosing

Salivary Testosterone, Male - with Topical Testosterone 12 hours after supplementation



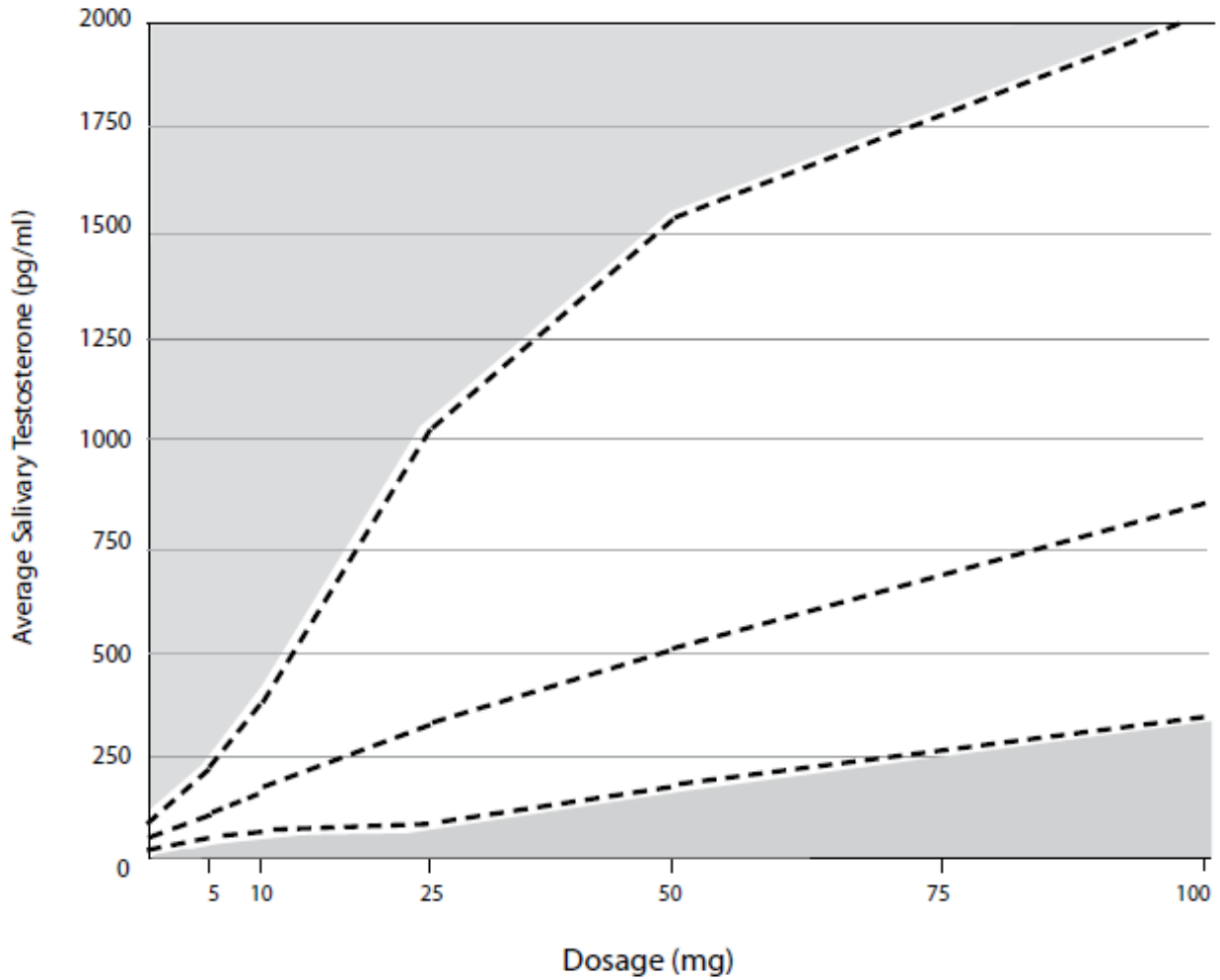
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Male - Topical Testosterone, 24 hours, 100 mg dosing

Salivary Testosterone, Male - with Topical Testosterone 24 hours after supplementation



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ADDITIONAL INFORMATION

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Patient Handout

Talk to your healthcare professional to make sure that you are reading your graph appropriately. Please do not change any supplementation based on these graphs without talking to your healthcare professional. These graphs are provided for educational information and cannot replace your healthcare professional's clinical skills in evaluating your lab values, your supplementation and most importantly your symptoms.

How to read the graphs: The graphs chart the *dosages of the hormones on the horizontal (x axis) and the lab values ZRT has observed on the vertical (Y axis).*

The lines – 80 percent of the people tested will be below the top line (red) and only 20 percent of the people tested will be below the bottom (blue) line. Thus, between the red and the blue line you can see where 60% of all people tested will have their lab results. The purple line in the middle represents the median. This is the point where the majority of people will have their lab results.

To find out where your values fall in the line, find your dosage on the x axis (horizontal) and your lab value on the y axis (vertical). Bring your fingers together; your left finger from the y axis moving horizontally and your right finger from the x axis moving upwards vertically. Mark this point. This is where your lab value is relative to the hormone dosage you are using. Now you can compare where your value compares to the ZRT database.

Why are levels different if everyone is taking the same dosage? Your laboratory levels are dependent on your dosage, the base of your cream or gel, how well your skin absorbs your creams, and how quickly your liver processes the hormones. Some people may have high values with small dosages and vice versa.

My labs are outside of the lines; what do I need to do? Remember that this is a tool and does not replace your healthcare professional's clinical experience. Some people may not have symptom relief until levels are higher than the top line or feel the best with levels less than the bottom 20% of people tested. You should not change your hormone supplementation without talking to your healthcare professional.

My value is above the red line; what do I do? Your level is higher than 80% of people taking the same dosage.

If your value is above the red line, it means that you produce higher lab levels for the same supplementation dosage than other people. You may also be reading your prescription incorrectly and may be taking a higher dosage than you think. Talk to your healthcare professional if you have any questions.

My value is below the blue line; do I need more? Remember that this is a guideline. Your value is less than 80% of people taking that same dosage. This might mean that you may be using a smaller dosage than you think, may not absorb 100% of your product, or may metabolize your hormones faster. These graphs are only for individuals using their hormones 12 hours or 24 hours prior to testing. If you used at a different timing interval, these graphs may not apply to you.

My hormone supplementation type doesn't have a graph? Graphs have not been provided for hormone supplementation where they are not helpful clinically or ZRT does not have sufficient data. It does not mean that you should change your hormones supplementation.

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