SELF-COLLECTION STRATEGIES FOR NONINVASIVE BIOSPECIMENS IN THE TIME OF COVID-19: OPPORTUNITIES AND GUIDELINES



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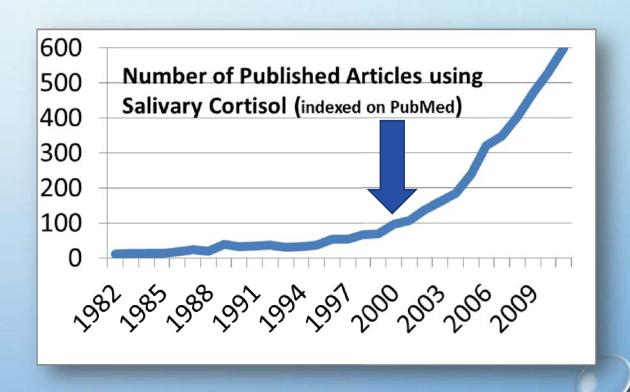






SALIVA: A BRIEF HISTORY

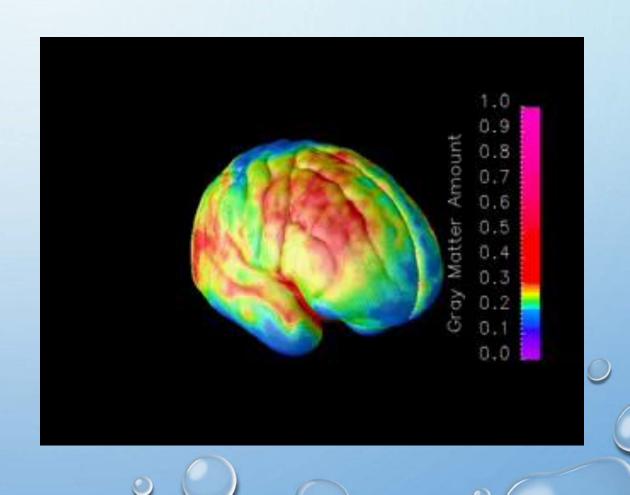
- OTHER BIOSPECIMENS
 - BLOOD
 - URINE
 - CSF
- CORTISOL PAVED WAY FOR OTHER HORMONES
 - TESTOSTERONE
 - DHEA
 - ESTRADIOL, ETC.





SALIVA: STRENGTHS

- STEROIDS GO EVERYWHERE!
 - MUST BE MANUFACTURED
 - LOCK-AND-KEY
 - LIPID SOLUBLE
 - ACINAR CELLS
 - BLOOD BRAIN BARRIER
 - CELL NUCLEI
- FREE VS BOUND HORMONES
 - BIOLOGICALLY ACTIVE FRACTION.
 - CARRIER PROTEINS





- SALIVA COLLECTION IS STRAIGHTFORWARD.
 - SUBJECTS CAN COLLECT IT THEMSELVES.
 - COLLECTION CAN TAKE PLACE IN A VARIETY OF LOCATIONS.
 - POINT-OF-CARE
 - NOT STRESSFUL OR INVASIVE.
- REPEATED MEASURES FEASIBLE





COVID-19

https://www.nih.gov/researchtraining/environmental-influenceschild-health-outcomes-echo-program seven-year research initiative, aims to determine what factors give children the highest probability of achieving the best health outcomes over their lifetimes.

To find answers to vital unanswered questions, ECHO taps into existing cohorts totaling about 50,000 children from racially, socioeconomically and geographically diverse backgrounds.

Biospecimens during COVID-19

Blood

• Biosafety Level 2 →

• Biosafety Level 2

Urine

Biosafety Level 2→

• Biosafety Level 2

Saliva

Biosafety Level 1→

• Biosafety Level 2

Hair

Biosafety Level 1→

• Biosafety Level 1

BS1

Gloves

Lab Coat recommended

General Lab Safety

BS2

BS1 and...

Safe Sharps

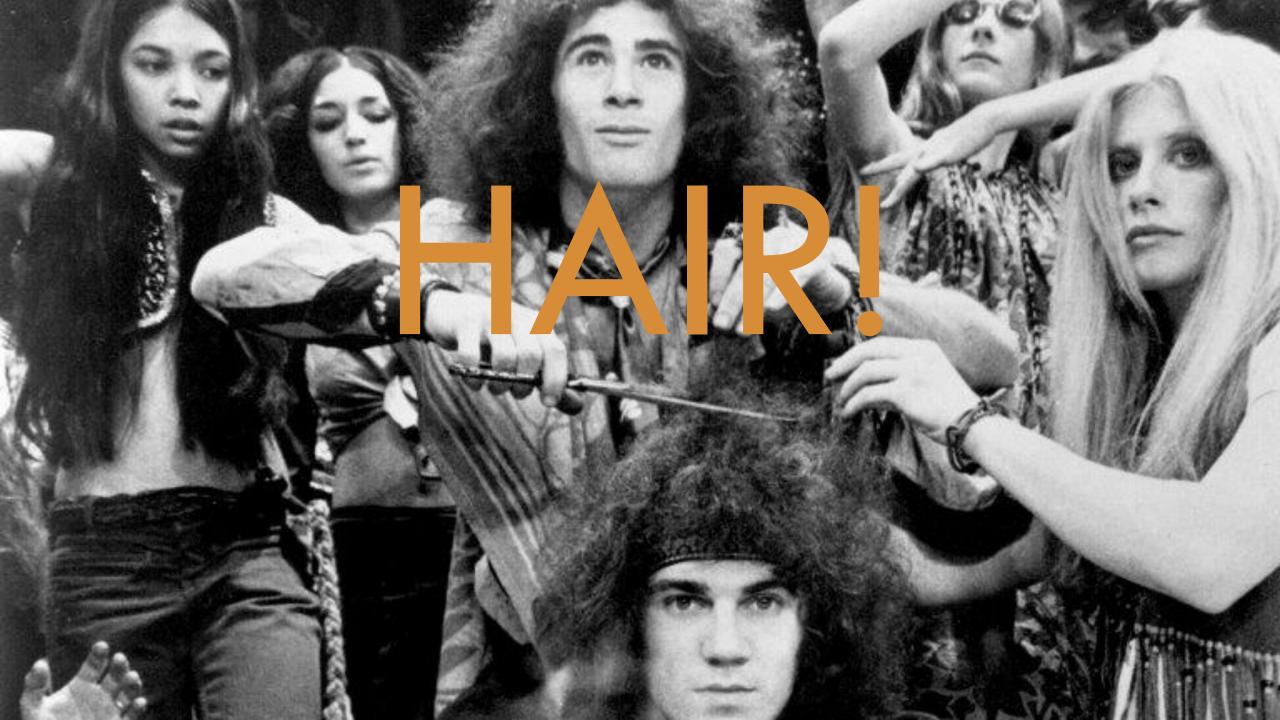
Face protection

Biosafety cabinet or other aerosol containment

Recommendation for controlled air flow

Biospecimens during COVID-19 (CDC recommendations)

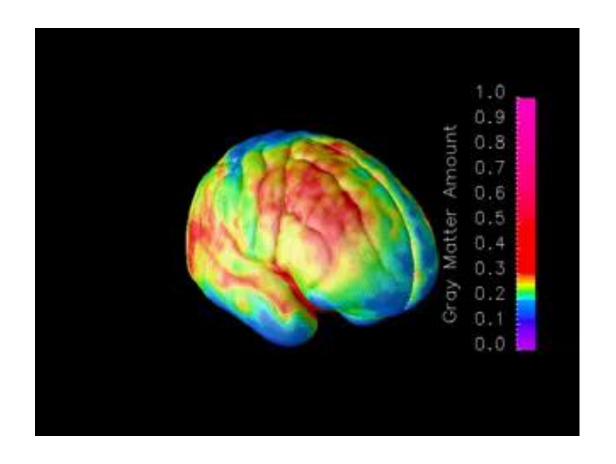
- Universal Precautions are best practice for infection control from <u>all</u> biospecimens
- Follow Standard Precautions when handling clinical specimens.
 Standard Precautions include hand hygiene and use of PPE, such as laboratory coats or gowns, gloves, and eye protection.
- Precautions should be taken in handling specimens that are suspected or confirmed for SARS-CoV-2. Timely communication between clinical and laboratory staff is essential to minimize the risk incurred in handling specimens from patients with possible SARS-CoV-2 infection. Such specimens should be labeled accordingly, and the laboratory should be alerted to ensure proper specimen handling.
- For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Type A1 or A2 BSC or additional precautions to provide a barrier between the specimen and personnel. EG: PPE, such as a surgical mask or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors.



What is the idea?

Brain maturation continues well into 20s

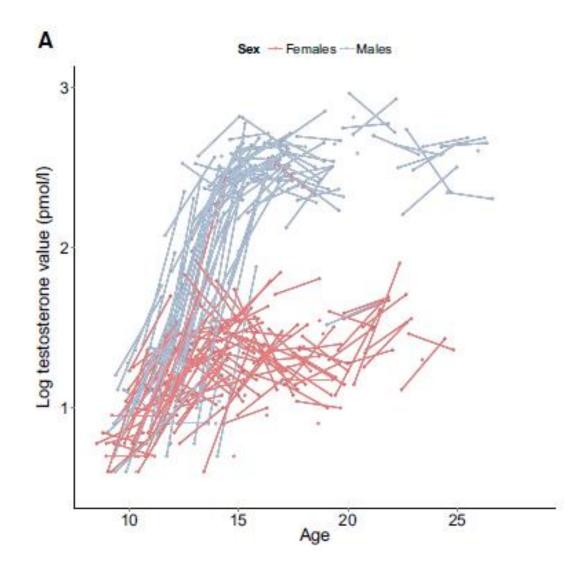
Rate of maturation influenced by puberty



What is the idea?

Puberty is driven by hormones

Hormones continue to change
long after "adult-like"



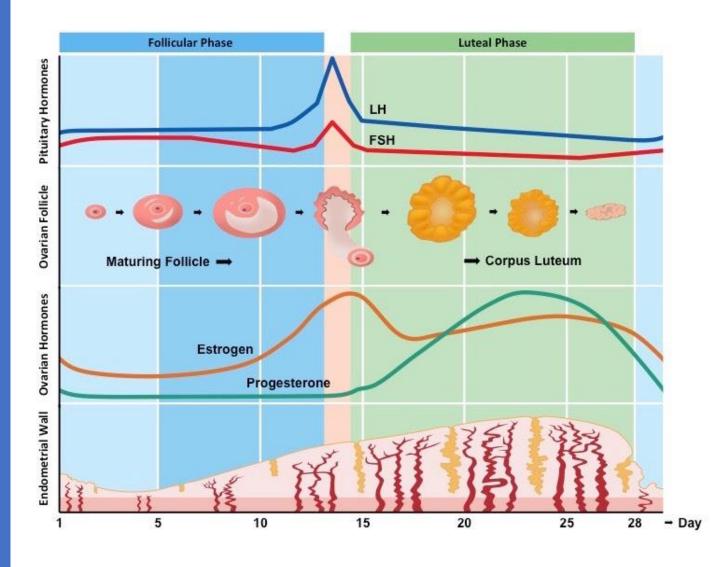
What is the idea?

Hormones are highly variable

With a day

Across days

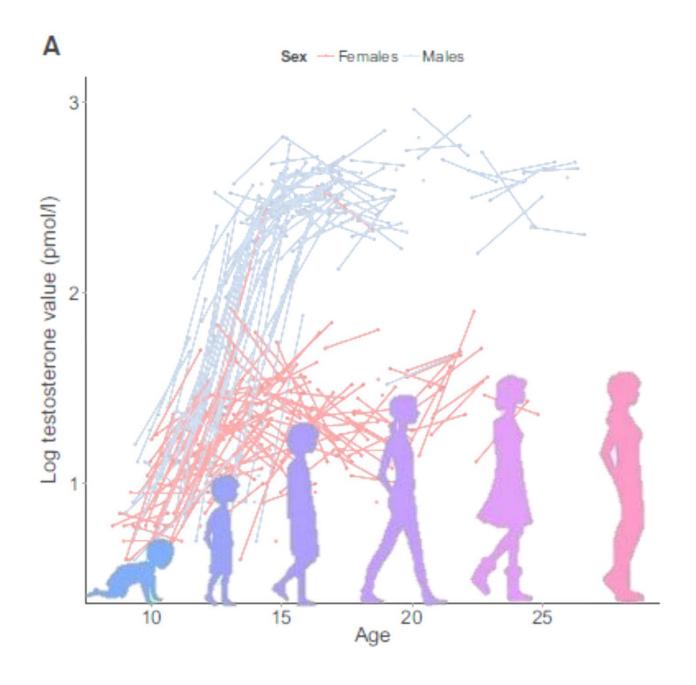
Across menstrual cycle



What is the need?

Hormone Measure that does not get overwhelmed by momentary variance

Hormone Measure that matches the timescale of development



What fills the need?

Hair captures 1-3 month of hormones

Matches the timescale of Development

Noninvasive

Passive diffusion

Biologically active

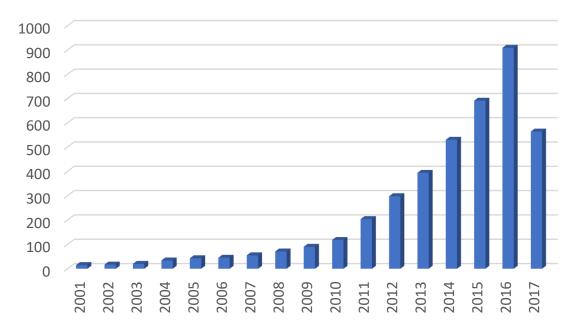


What is Commercial need?

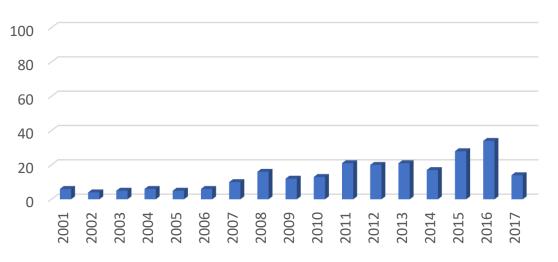
By Analogy, Hair Cortisol is growing market

Hormone Measure that matches the timescale of development

Hair Cortisol Papers Published



Papers Published that mention Hair Testosterone





TIME TO BE A BARBER









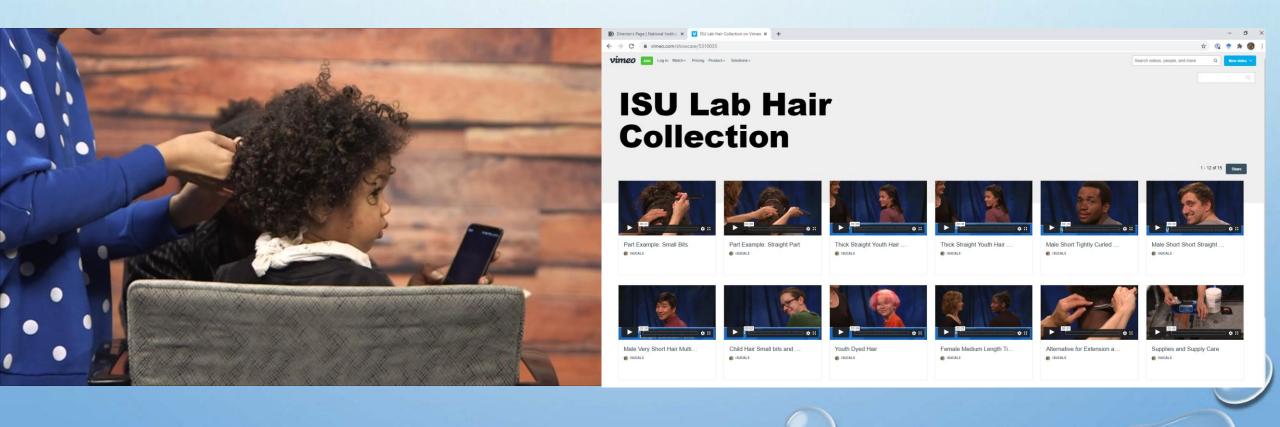






Straight-line hair collection method

HTTPS://VIMEO.COM/SHOWCASE/5310035





QUALITY PLACEMENT IN FOIL SHEETS

Example 1. Good example of long hair



Example 2. Good example of short hair



- PLACE HAIR SAMPLES IN A FOIL PACKET (SEE EXAMPLES).
 - FOR LONGER HAIR, LOOP THE SAMPLE WITHOUT BENDING THE HAIR SHARPLY (SEE EXAMPLE 1& 9).
 - CLEARLY DELINEATE THE SCALP END OF THE HAIR BY BANDING THE
 HAIR NEAR THE SCALP END, NOTING THE SCALP END MARKER ON THE
 FOIL, OR PREFERABLY BOTH (SEE EXAMPLE 1 & 2).

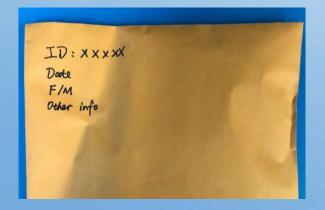


GETTING READY TO SHIP

Example 3. Example of foil envelope



Example 5. Example of envelope



Example 4. Example of labeled foil envelope



- FOLD THE FOIL PACKET SUCH THAT IT MAKES AN ENVELOPE OVER THE HAIR (SEE EXAMPLE 3).
- LABEL THE FOIL ENVELOPE WITH ALL RELEVANT SAMPLE INFORMATION (SEE EXAMPLE 4).
- LABEL THE MANILA ENVELOPE (SEE EXAMPLE 5).
- KEEP THE SAMPLE AT ROOM TEMPERATURE.
- LABEL SAMPLES IN A CLEAR AND LEGIBLE MANNER.
 - PLEASE INCLUDE PARTICIPANT GENDER WHEN POSSIBLE.
- PLEASE USE A TRACKED SHIPPING METHOD.

Example 6. Wrong example of sealed foil envelope



Example 8. Wrong example of taped short hair



WHAT NOT TO DO...

Example 7. Wrong example of taped long hair



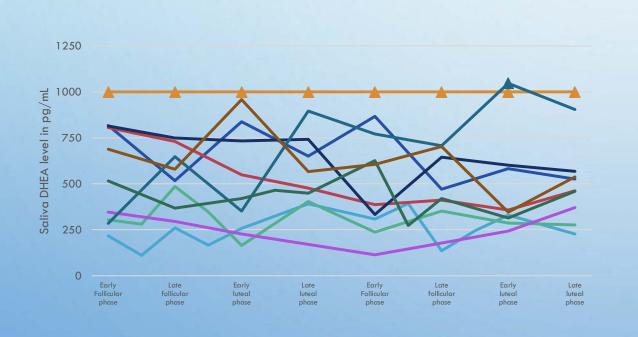
Example 9. Wrong sample of over-bent long hair

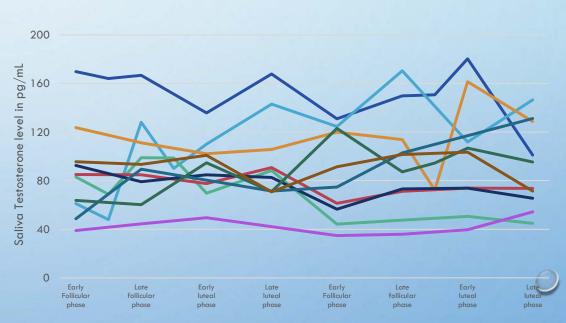


- PLEASE DO NOT LACE A LABEL OVER THE EDGE OF THE FOIL (THIS WILL HAVE TO BE CUT AND PARTICIPANT INFORMATION WILL BE LOST) (SEE EXAMPLE 6).
- PLEASE DO NOT TAPE, GLUE OR OTHERWISE USE ADHESIVES TO ATTACH THE HAIR TO THE FOIL (SEE EXAMPLE 7 & 8).
- PLEASE DO NOT USE BIOHAZARD BAGS.
- PLEASE DO NOT SHIP HAIR WITH SALIVA.



DID HAIR HELP?





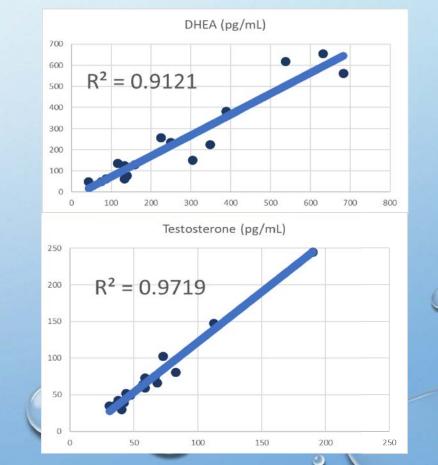


DID HAIR HELP?

- STRONG CORRELATIONS OF ONE SEGMENT TO THE NEXT (COLLECTED ONE MONTH LATER)
- SIGNIFICANT CORRELATIONS WITH SALIVA WHEN SALIVA WAS AVERAGED

SOOOOO MANY FUTURE DIRECTIONS





SO DID I MENTION SWEAT?



